NOVARTIS AG Form 20-F January 23, 2013

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Part III

NOVARTIS GROUP INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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As filed with the Securities and Exchange Commission on January 23, 2013

# 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, 2012

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)

Felix R. Ehrat Group General Counsel

Novartis AG CH-4056 Basel Switzerland 011-41-61-696-9511 felix.ehrat@novartis.com

(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
American Depositary Shares
each representing 1 share,
nominal value CHF 0.50 per share,
and shares

Name of each exchange on which registered 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:

2,420,620,174 shares

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

Yes ý No o

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 o No ý

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 ý No o

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 ý

Accelerated filer o

Non-accelerated filer o

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

o U.S. GAAP ý International Financial Reporting Standards as issued by the International Accounting Standards Board o 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 o Item 18 o

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 o No ý

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#### INTRODUCTION

Novartis AG and its consolidated affiliates (Novartis or the Group) 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).

#### **USE OF CERTAIN TERMS**

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 (EU) are to the European Union and its 27 member states and references to "Americas" are to North, Central (including the Caribbean) and South America, 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 EMA's Committee for Medicinal Products for Human Use; references to "ADS" or "ADSs" are to Novartis American Depositary Shares, and references to "ADR" or "ADRs" are to Novartis American Depositary Receipts; references to the NYSE are to the New York Stock Exchange, and references to the SIX are to the SIX Swiss Exchange. 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. You will find the words "we," "our," "us" and similar words or phrases in this Form 20-F. We use those words to comply with the requirement of the US Securities and Exchange Commission to use "plain English" in public documents like this Form 20-F. For the sake of clarification, 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.

#### 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, which can be identified by terminology such as "planned," "expected," "will," "potential," "pipeline," "outlook," or similar expressions, 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 outcomes of our efforts to improve the quality standards at any or all of our manufacturing sites; or regarding potential future sales or earnings of the Group or any of its divisions in the near- and long-term; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such 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 Group will be successful in its efforts to improve the quality standards at any or all of our manufacturing sites, or that we will succeed in restoring or maintaining production at any particular sites. Neither can there be any guarantee that the Group, or any of its divisions, will achieve any particular financial results, either in

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the near-term or in the long-term. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection, including the ultimate extent of the impact on the Group of the loss of patent protection on key products which commenced last year and will continue this year; unexpected product manufacturing and quality issues, including the potential outcomes of our efforts at the Sandoz and Alcon sites that are subject to Warning Letters, and with respect to our efforts to restart production of products formerly produced at the Consumer Health manufacturing facility at Lincoln, Nebraska; government, industry, and general public 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, shareholder litigation, government investigations and intellectual property disputes; competition in general; uncertainties regarding the effects of the ongoing global financial and economic crisis, including the financial troubles in certain Eurozone countries; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; uncertainties necessarily involved in long-term financial projections; uncertainties involved in the development of new healthcare products; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet. Some of these factors are discussed in more detail herein, 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 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.

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#### 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, 2012, 2011 and 2010 are included in "Item 18. Financial Statements" in this Form 20-F.

The results of our Medical Nutrition and Gerber Business Units are shown as discontinued operations for all periods presented, following their divestment in 2007.

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.

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	Year Ended December 31,				
	2012 2011 2010 2009 200				
	(\$ millions, except per share information)				
INCOME STATEMENT DATA			_		
Net sales from continuing operations	56,673	58,566	50,624	44,267	41,459
Operating income from continuing operations	11,511	10,998	11,526	9,982	8,964
Income from associated companies	552	528	804	293	441
Interest expense	(724)	(751)	(692)	(551)	(290)
Other financial (expense)/income	(96)	(2)	64	198	384
Income before taxes from continuing operations	11,243	10,773	11,702	9,922	9,499
Taxes	(1,625)	(1,528)	(1,733)	(1,468)	(1,336)
Net income from continuing operations	9,618	9,245	9,969	8,454	8,163
Net income from discontinued operations	•	,			70
•					
Group net income	9,618	9,245	9,969	8,454	8,233
oroup not meome	,,010	>,= :0	2,9202	0,101	0,200
Attributable to:					
Shareholders of Novartis AG	9,505	9.113	9,794	8,400	8,195
Non-controlling interests	113	132	175	54	38
Operating income from discontinued operations	113	132	173	51	70
Basic earnings per share (\$):					70
Continuing operations	3.93	3.83	4.28	3.70	3.59
Discontinued operations	5.75	3.03	1.20	3.70	0.03
Total	3.93	3.83	4.28	3.70	3.62
Diluted earnings per share (\$):	5.75	3.03	1.20	3.70	3.02
Continuing operations	3.89	3.78	4.26	3.69	3.56
Discontinued operations	3.07	5.70	1.20	3.07	0.03
Total	3.89	3.78	4.26	3.69	3.59
Cash dividends <sup>(1)</sup>	6,030	5,368	4,486	3,941	3,345
Cash dividends per share in CHF <sup>(2)</sup>	2.30	2.25	2.20	2.10	2.00
Cuon di l'actido per onare in Citi	2.50	2.23	2.20	2.10	2.00

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

<sup>(2)</sup>Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2012 will be proposed to the Annual General Meeting on February 22, 2013 for approval.

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	Year Ended December 31,				
	2012	2011	2010	2009	2008
		(\$	millions)		
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial					
instruments	8,119	5,075	8,134	17,449	6,117
Inventories	6,744	5,930	6,093	5,830	5,792
Other current assets	13,141	13,079	12,458	10,412	8,972
Non-current assets	96,212	93,412	96,633	61,814	57,418
Total assets	124,216	117,496	123,318	95,505	78,299
Trade accounts payable	5,593	4,989	4,788	4,012	3,395
Other current liabilities	18,458	18,159	19,870	15,458	13,109
Non-current liabilities	30,946	28,408	28,891	18,573	11,358
Total liabilities	54,997	51,556	53,549	38,043	27,862
Issued share capital and reserves attributable to shareholders of Novartis AG	69,093	65,844	63,196	57,387	50,288
Non-controlling interests	126	96	6,573	75	149
Total equity	69,219	65,940	69,769	57,462	50,437
Total liabilities and equity	124,216	117,496	123,318	95,505	78,299
Net assets	69,219	65,940	69,769	57,462	50,437
Outstanding share capital	909	895	832	825	820
Total outstanding shares (millions)	2,421	2,407	2,289	2,274	2,265

## Cash Dividends per Share

(1)

Cash dividends are translated into US dollars at the Reuters/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 ADSs.

		<b>Total Dividend</b>	<b>Total Dividend</b>	
	Month and	per share	per share	
Year Earned	Year Paid	(CHF)	(\$)	
2008	February 2009	2.00	1.72	
2009	March 2010	2.10	1.95	
2010	March 2011	2.20	2.37	
2011	March 2012	2.25	2.48	
2012(1)	March 2013	2.30	2.51(2)	

Dividend to be proposed at the Annual General Meeting on February 22, 2013 and to be distributed March 1, 2013

Translated into US dollars at the 2012 Reuters/Bloomberg Market System December 31, 2012 rate of \$1.09 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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#### **Exchange Rates**

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Reuters/Bloomberg Market System. The exchange rate in effect on January 17, 2013, as found on Reuters Market System, was CHF 1.00 = \$1.07.

#### Year ended December 31.

Teal chaca December 51,				
(\$ per CHF)	Period End	$Average^{(1)}$	Low	High
2008	0.94	0.93	0.82	1.02
2009	0.97	0.92	0.84	1.00
2010	1.06	0.96	0.86	1.07
2011	1.06	1.13	1.06	1.25
2012	1.09	1.07	1.02	1.12
<b>Month</b>				
August 2012			1.02	1.05
September 2012			1.04	1.08
October 2012			1.06	1.08
November 2012			1.05	1.08
December 2012			1.07	1.10
January 2013 (through January 17, 2013)			1.07	1.10
•				

(1)

Represents the average of the exchange rates on the last day of each full month during the year.

#### 3.B Capitalization and Indebtedness

Not applicable.

#### 3.C Reasons for the offer and use of proceeds

Not applicable.

#### 3.D Risk Factors

Our businesses face significant risks and uncertainties. You should carefully consider all of the information set forth in this annual report on Form 20-F and in other documents we file with or furnish to the SEC, including the following risk factors, before deciding to invest in any Novartis securities. Our business as well as our financial condition or results of operations could be materially adversely affected by any of these risks, as well as other risks and uncertainties not currently known to us or not currently deemed to be material.

#### **Risks Facing Our Business**

Our patented pharmaceuticals businesses, and other key products, face, and will continue to face, important patent expirations and aggressive generic 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 including the loss of exclusivity on *Diovan*, our best-selling product, which began in the EU in 2011, and occurred in the US in 2012 and will continue in Japan in 2013 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 valsartan, the active ingredient of *Diovan/Co-Diovan/Diovan HCT* (high blood pressure), expired in the major countries of the EU in November 2011, and generic competitors have launched there. In addition, patent protection expired in the US in September 2012, and generic versions of *Diovan HCT* have launched in the US. Generic versions of *Diovan* monotherapy have not yet launched in the US but could potentially launch at any time. In addition, patent protection for *Diovan* is scheduled to expire in Japan in 2013, and 2016 for *Co-Diovan* (including patent term extensions). The active ingredient valsartan is also used in the single-pill combination therapies *Exforge* and *Exforge HCT* (high blood pressure). While market exclusivities for *Exforge/Exforge HCT* will remain in the EU and Japan due to regulatory exclusivities, there is a risk that generic manufacturers may circumvent regulatory exclusivity and gain approval of a combination valsartan-amlodipine product in Europe. In the US, under a license agreement with a generics manufacturer, the product is expected to face generic competition beginning in October 2014.

The patent on *Femara* (cancer) expired in 2011 in the US and in major European markets, and generic competitors have launched in those markets.

The patent on zoledronic acid, the active ingredient in *Zometa* (cancer), as well as in *Reclast/Aclasta* (osteoporosis), expired in 2012 in a limited number of smaller markets, and will expire in 2013 in the US and in other major markets. However, certain forms or uses of these products are covered by additional patents with later expiration dates in certain markets.

The patent on the active ingredient in *Gleevec/Glivec* (cancer) will expire in 2015 in the US, in 2016 in the major EU countries and 2014 in Japan, in each case including extensions. However, the product is protected by additional patents claiming innovative features of *Gleevec/Glivec*.

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

In 2013, the impact of generic competition on our net sales is expected to be as much as \$3.5 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

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product and obtaining regulatory approval to market it; the number of generic competitor products approved, and whether, in the US, a single competitor is granted an exclusive marketing period; and the geographies in which generic competitor products are approved, including the strength of the market for generic pharmaceutical products in such geographies 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.

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

Our ability to continue to grow our business and to replace sales lost due to the end of market exclusivity 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 various 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 pharmaceutical 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, or that we will not achieve our goals and, accordingly, may be forced to abandon a product in which we have invested substantial amounts of time and money. Reasons for delays may include: failure of the product candidate in preclinical studies; difficulty enrolling patients in clinical trials or delays or clinical trial holds at clinical trial sites; delays in completing formulation and other testing and work necessary to support an application for regulatory approval; adverse reactions to the product candidate or indications or other safety concerns; insufficient clinical trial data to support the safety or efficacy of the product candidate; an inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-effective manner; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured. In addition, FDA and other governmental health authorities have recently begun to intensify their scrutiny of pharmaceutical companies' clinical development activities, both with respect to compliance with regulations related to the conduct of clinical trials, and with respect to their interpretations of the clinical trial requirements necessary to support a product submission. This has added to the obstacles and costs we face in bringing new products to market.

Our other divisions face similar challenges in developing and bringing to market new products. Alcon's Ophthalmic Pharmaceuticals products, Vaccines and Diagnostics' Vaccine products, and Animal Health products all must be developed and approved in accordance with essentially the same processes as faced by our Pharmaceuticals Division. Nearly all of our other products face similarly difficult

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development and approval processes. At Alcon, management has announced plans to make significant investments in research and development in the coming years to develop new eyecare products to replace sales lost to generic competition and to grow its business. Vaccines and Diagnostics has, and continues to expend considerable time and resources to fully develop and bring to market new vaccines, including two, *Menveo* and *Bexsero*, to combat different strains of meningococcal disease in patients of a wide range of age groups. Our Animal Health Division seeks to bring new products to market from time to time. If these efforts do not bear significant fruit, they could have a material adverse effect on the medium to long-term success of the divisions, and of the Group as a whole.

In addition, our Sandoz Division has made, and expects to continue to make, significant investments in the development of differentiated, "difficult-to-make" generic products, including biotechnology-based, "biologic" medicines intended for sale as bioequivalent or "biosimilar" generic versions of currently-marketed biotechnology products. While the development of such products can be significantly less costly and complex than the development of the equivalent originator medicines, it can often be significantly more costly and complex than for non-differentiated generic products. In addition, to date, many countries do not yet have an established 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 (including the significant number of important products which have begun, and will continue to face generic competition in the near future), or are displaced by competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations. For a description of the approval processes which must be followed to market our products, see the sections headed "Regulation" included in the descriptions of our four operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

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

Following a series of widely publicized issues in recent years, health regulators are increasingly focusing on product safety. The Obama Administration has publicly emphasized the importance of enforcing US drug safety regulations. In addition, governmental authorities around the world have paid increased attention to the risk/benefit profile of pharmaceutical products with an increasing emphasis on product safety and on examining whether new products offer a significant benefit over older products in the same therapeutic class. These developments have led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals for pharmaceutical products has become even more challenging.

In addition, for the same reason, the post-approval regulatory burden has been increasing. Approved drugs have increasingly been subject to requirements such as risk evaluation and mitigation strategies (REMS), risk management plans, comparative effectiveness studies, health technology assessments and requirements to conduct post-approval Phase IV clinical trials to gather far more detailed safety and other data on products. These requirements have the effect of making the maintenance of regulatory approvals and achieving reimbursement for our products increasingly expensive, and further heightening the risk of recalls, product withdrawals, or loss of market share.

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

#### Our business is increasingly affected by pressures on pricing for our products.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly. These pressures are particularly strong given the ongoing effects of the recent global economic and financial crisis, including the continuing debt crisis in certain countries in Europe, and the risk of a similar crisis in the US. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. These ongoing pressures affect all of our businesses that rely on reimbursement including Pharmaceuticals, Alcon, Sandoz and Vaccines and Diagnostics and involve government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing systems, payors limiting access to innovative medicines based on cost-benefit analyses, an increase in imports of drugs from lower-cost countries to higher-cost countries, shifting of the payment burden to patients through higher co-payments, limiting physicians' ability to choose among competing medicines, mandatory substitution of generic drugs for the patented equivalent, and growing pressure on physicians to reduce the prescribing of patented prescription medicines. Such initiatives include the 2010 enactment of healthcare reform in the US, its implementation, and ongoing efforts by the US Government to find additional savings from government healthcare programs.

As a result of such measures, we faced downward pricing pressures on our patented and generic drugs in many countries in 2012. For example, in November 2012, the UK's National Institute for Health and Clinical Excellence (NICE) recommended that the UK National Health Service cease funding the use of our product *Xolair* to treat asthma, on cost-effectiveness grounds, despite a prior 2007 finding by NICE that use of *Xolair* was cost-effective. Similarly, in November 2011, NICE declined on cost-effectiveness grounds to recommend National Health Service funding of the use of our product *Lucentis* to treat diabetic macular edema, despite the product's having been approved by the relevant health authorities for the indication. Subsequently, in October 2012, NICE reversed its decision, recommending that *Lucentis* be reimbursed for a limited subset of patients with this condition, but only after we offered NICE a significant discount on pricing. Similarly, depending on the outcome of recently initiated preliminary court proceedings, a German government agency, the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG), may shortly begin a Health Technology Assessment of our products *Galvus* and *Eucreas* for Type 2 Diabetes, which can be a step towards a request that we significantly reduce the prices at which we sell the products. In China, the National Development and Reform Commission imposed a price cut on our Oncology product *Femara*. In the US, under the Affordable Care Act, there is a newly created entity, the Independent Payment Advisory Board, which has been granted unprecedented authority to implement broad actions to reduce future costs of the Medicare program. This could include required prescription drug discounts or rebates.

We expect these efforts to control costs to continue in 2013 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."

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

We are obligated to comply with the laws of the approximately 140 countries in which we sell products, covering an extremely wide range of activities. To that end, we have a significant global compliance with law program in place. Nonetheless, despite our efforts, any failure to comply with law could lead to substantial liabilities that may not be covered by insurance, and could affect our business and reputation.

In particular, in recent years, there has been a trend of increasing government investigations and litigations against companies operating in the industries of which we are a part, both in the US and in an increasing number of countries around the world. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including proceedings regarding product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, sales and marketing practices, 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 corruption, marketing practices, insider trading, antitrust, trade restrictions, embargo legislation and data privacy. Responding to such investigations is costly, and requires an increasing amount of management's time and attention. In addition, such investigations may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the US and other countries, and may lead to litigation. These factors have contributed to recent decisions by us and other companies in our industry, when deemed in their interest, to enter into settlement agreements with governmental authorities around the world prior to any formal decision by the authorities. These settlements have involved and may continue to involve large cash payments, including the potential repayment of amounts allegedly obtained improperly and other penalties, including treble damages. In addition, settlements of healthcare fraud cases often require companies to enter into corporate integrity agreements, which are intended to regulate company behavior for a period of years. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

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

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

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

For more detail regarding specific legal matters currently pending against us and provisions for such matters, see "Item 18. Financial Statements" note 20." See also "Our reliance on third parties for the performance of key business functions heightens the risks faced by our businesses" below.

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

The products we market and sell are either manufactured at our own dedicated manufacturing facilities or by third parties. In either case, we must ensure that all manufacturing processes comply with current Good Manufacturing Practices (cGMP) and other applicable regulations, as well as with our own high quality standards. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA, and such health authorities continue to intensify their scrutiny of manufacturers' compliance with such requirements. If we or our third-party suppliers fail to comply fully with these requirements then we could be required to shut down our production facilities or production lines. This could lead to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. And such shortages or shut downs have led to and could continue to lead to significant losses of sales revenue and to potential third-party litigation. In addition, health authorities have in some cases imposed significant penalties for such failures to comply with cGMP. A failure to comply fully with cGMP could also lead to a delay in the approval of new products to be manufactured at the impacted site.

Like our competitors, we have faced, and continue to face, significant manufacturing issues. For example, in November 2011, we received a Warning Letter from the FDA with respect to three of our Sandoz Division's facilities in Broomfield, Colorado, Wilson, North Carolina, and Boucherville, Canada. The Warning Letter raised concerns regarding these facilities' compliance with FDA cGMP regulations. It stated that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending applications or supplements listing Novartis affiliates as a drug manufacturer. In addition, FDA may refuse requests to issue export certificates to our Sandoz US affiliate, or import certificates to our Sandoz Canada affiliates. The letter further states that other federal agencies may take the Warning Letter into account when considering the award of contracts. In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site. The division is on track to meet its remediation commitments for the other two sites as well.

In addition, in December 2011, we suspended operations and shipments from the OTC Division facility located at Lincoln, Nebraska, which also produces certain products for our Animal Health Division. This action was taken to accelerate maintenance and other improvement activities at the site. Subsequently, in January 2012, we recalled certain OTC Division products that were produced at the Lincoln facility. We made progress in 2012 in the remediation of quality issues at Lincoln, and have outsourced the production of certain Lincoln products. However, as of the date of this Form 20-F, it is not possible to determine when the plant will resume significant operations.

In December 2012, our Alcon Division received an FDA Warning Letter following an inspection at the *LenSx* laser manufacturing site in Aliso Viejo, California. Alcon has responded in writing to the FDA and is committed to addressing these observations and collaborating with the Agency to ensure that they are fully resolved. The items noted in the Warning Letter do not affect the safety or effectiveness of the *LenSx* laser, or impact our ability to sell the product.

As a result of such manufacturing issues, we have suffered and may continue to suffer significant losses in sales and market share. In addition, we have been required to expend considerable resources on the remediation of the issues at these sites. Should we fail to complete the planned improvements at the sites in agreement with the FDA in a timely manner, then we may suffer significant additional losses in sales and drainage of resources, and we could be subject to legal action without further notice including, without limitation, seizure and injunction.

In addition, we currently have several other manufacturing sites which are being upgraded to address advances in technology, improve quality, and assure consistency of product supply, either at our own initiative, or in accordance with commitments to FDA and other health authorities around the world. Such efforts have required us to make significant investments in our production facilities. Ultimately, there can

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be no guarantee of the outcome of any of these matters. Nor can there be any guarantee that we will not face similar such issues in the future, or that we will successfully manage such issues when they arise.

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

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

Finally, in addition to potential liability for government penalties, because our products are intended to promote the health of patients, for some of our products, any supply disruption or other production issue could subject us to lawsuits or to allegations that the public health, or the health of individuals, has been endangered.

In sum, a disruption in the supply of certain key products whether as a result of a failure to comply with applicable regulations, the fragility of the production process, or our failure to accurately predict demand could have a material adverse effect on our business, financial condition or results of operations.

#### The continuing global economic and financial crisis may have a material adverse effect on our results.

Many of the world's largest economies and financial institutions continue to be impacted by the ongoing global economic and financial crisis, with some continuing to face financial difficulty, a decline in asset prices, 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. Such uncertain economic 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, the ongoing debt crisis 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." The debt crisis has also given rise to concerns that some countries may not be able to pay us for our products at all. This situation could further deteriorate as a result of potential developments in countries of key concern such as Greece, Italy, Portugal and Spain, each of which continues to face significant concerns regarding its ability to repay its sovereign debt obligations.

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,

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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 sovereign risk from business interactions directly with fiscally-challenged government payers. See also "Our reliance on 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 crisis may also result in a lower return on our financial investments, and a lower value on some of our assets. Alternately, the financial crisis may lead to inflation, which could lead to higher interest rates, which would increase our costs of raising capital.

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

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

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

In the past year, the US dollar, our reporting currency, has significantly increased in value against other world currencies. However, in the prior year, the US dollar suffered significant decreases in value. In addition, in recent years, unresolved fiscal issues in the US and in many European economies, and investor concerns about the future of the Euro, have led to the flight of investor capital to the perceived safety of the Swiss franc, causing the Swiss franc to rise significantly in value. Because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including expenditures in Swiss francs which are significantly higher than our revenues in Swiss francs, this volatility can have a significant and often unpredictable impact on our reported net sales and earnings. In 2012, 36% of our net sales were made in US dollars, 25% in euros, 9% in Japanese yen, 2% in Swiss francs and 28% in other currencies. During the same period, 39% of our expenses arose in US dollars, 25% in euros, 13% in Swiss francs, 5% in Japanese yen and 18% in other currencies. As has happened in the recent past, changes in exchange rates between the US dollar and other currencies can result in increases or decreases in our sales, costs and earnings as expressed in US dollars. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured in US dollars and the components of shareholders' equity. In addition, there is a risk that certain countries could devalue their currency. If this occurs then it could impact the effective prices we would be able to charge for our

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products and also have an adverse impact on both our consolidated income statement and currency translation adjustments included in our consolidated equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5.A Operating Results Effects of Currency Fluctuations" and "Item 18. Financial Statements note 16."

#### We may not successfully complete and integrate strategic acquisitions to expand or complement our business.

As part of our growth strategy, we evaluate and pursue strategic business acquisitions to expand or complement our business. Such ventures may bring new products or services, increased market share or new customers to our prominent position in the healthcare industry. We cannot ensure that suitable acquisition candidates will be identified. Acquisition activities can be thwarted by overtures from competitors for the targeted candidates, governmental regulation (including market concentration limitations) and replacement product developments in our industry. Further, after an acquisition, successful integration of the venture can be complicated by corporate cultural differences, difficulties in retention of key personnel, customers and suppliers, and coordination with other products and processes. Also, acquisitions could divert management's attention from our existing business, and could result in liabilities being incurred that were not known at the time of acquisition or the creation of tax or accounting issues. If we fail to timely recognize or address these matters or to devote adequate resources to them, we may fail to achieve our growth strategy or otherwise not realize the intended benefits of any acquisition.

#### An increasing amount of 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 2012, for example, we recorded intangible asset impairment charges of \$286 million. These relate to impairment charges of \$211 million for various impairment charges in the Pharmaceuticals Division and \$75 million in all other divisions. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing impact of impairment charges on our results of operations, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Impairment of Long-Lived Intangible and Tangible Assets" and "Item 18. Financial Statements note 11."

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

As of December 31, 2012 we had \$13.8 billion of non-current financial debt and \$5.9 billion of current financial debt. Our current and future 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 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.

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

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

At a time of slowing growth in sales of healthcare products in industrialized countries, many emerging markets have experienced comparatively strong economies, leading to proportionately higher growth and an increasing contribution to the industry's global performance. In 2012, we generated \$13.8 billion, or approximately 24% (2011: 24%) of net sales from Emerging Growth Markets which include all markets except the Established Markets of the US, Canada, Western Europe, Australia, New Zealand and Japan as compared with \$42.8 billion, or approximately 76% (2011: 76%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 5.9% in constant currency in 2012, compared to -1.7% sales growth in constant currency in the Established Markets during the same period. As a result of this trend, we have been taking steps to increase our presence in the Emerging Growth Markets. For example, in order to bolster our ability to recruit and train commercial associates in China, we have created the Novartis China University to systematically train all Novartis commercial associates in the science of the Novartis medicines for which they are responsible. In Russia, we are working with the Yaroslavl region northeast of Moscow, and have established a new Regional Hypertension Center and a public education campaign. Three pilot sites now offer hypertension intervention tools. In addition, we are also focusing our efforts on Africa, where we expect rising demand for healthcare.

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 ongoing global financial crisis, or may have very limited resources to spend on healthcare. See " The continuing economic and financial crisis may have a material adverse effect on our results" above. Many of these countries 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, or we may be required to rely on third-party agents, in either case putting us at risk of liability. See " Legal proceedings may have a significant

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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.

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

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

Our Sandoz Division achieves significant revenue opportunities when it secures and maintains exclusivity periods granted for generic products in certain markets particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act and when it is able to develop differentiated products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz. In addition, the division faces intense competition from patented pharmaceuticals companies, which commonly take aggressive steps to limit the availability of exclusivity periods or to reduce their value, and from other generic pharmaceuticals companies, which aggressively compete for exclusivity periods and for market share of generic products which may be identical to certain of our generic products. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction. See also " Our research and development efforts may not succeed in bringing new products to market, or to do so cost-efficiently enough, or in a manner sufficient to grow our business and replaced lost revenues and income" above, with regard to the risks involved in our efforts to develop differentiated generic products.

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

We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. We are required to make significant assumptions and estimates about future events in calculating the present value of expected future expense and liability related to these plans. These include assumptions about discount rates we apply to estimated future liabilities and rates of future compensation increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by Novartis may differ materially from the actual results we experience due to changing market and economic conditions (including the effects of the ongoing global economic and debt crisis, which, to date, have resulted in extremely low interest rates), higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the discount rate we apply in determining the present value of expected future obligations of one-quarter of one percent would have increased our year-end defined benefit obligation by \$838 million. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. Further, additional employer contributions might be required if the funding level determined based on local rules falls below a pre-determined level. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Retirement and

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other post-employment plans" and "Item 18. Financial Statements note 25". See also " The continuing economic and financial crisis 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.

#### Our OTC Division faces adverse impacts from increased competition, as well as potential questions of safety and efficacy.

Our OTC Division sells over-the-counter medicines, many of which contain ingredients also sold by competitors in the OTC industry. Particularly in the US, our branded OTC products compete against "store brand" products that are made with the same active ingredients as ours. These products do not carry our trusted brand names, but they also do not carry the burden of the expensive advertising and marketing that helped to establish demand for the product. As a result, the store brand products may be sold at lower prices. In recent years, consumers have increasingly begun to purchase store brand OTC products instead of branded products. In addition, in recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain products sold by our OTC Division and its competitors. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. For example, in 2010, the FDA undertook a review of one cough medicine ingredient to consider whether over-the-counter sales of the ingredient remained appropriate. While FDA has not, to date, changed the ingredient's status, further regulatory or legislative action may follow, and litigation has often followed actions such as these, particularly in the US. Additional actions and litigation regarding OTC products are possible in the future. These trends have had, and may continue to have, a significant adverse effect on the success of our OTC Division. See also " The continuing economic and financial crisis may have a material adverse effect on our results" above.

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

Our industry has been increasingly 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 be potentially life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm in the longer term.

## Ongoing consolidation among our distributors may increase both the purchasing leverage of key customers and the concentration of credit risk.

Increasingly, a significant portion of our global sales are made to a relatively small number of US drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally are all in the US, and accounted for approximately 10%, 9% and 8%, respectively, of Group net sales in 2012. The largest trade receivables outstanding were for these three customers, amounting to 8%, 7% and 6%, respectively, of the Group's trade receivables at December 31, 2012. The

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trend has been toward further consolidation among our distributors, especially in the US. As a result, our distributors 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 and training qualified individuals. The loss of the service of key members of our organization particularly senior members of our scientific and management teams could delay or prevent the achievement of major business objectives. In addition, the success of our research and development activities is particularly dependent on our ability to attract and retain sufficient numbers of high-quality researchers and development specialists.

Future economic growth will demand more talented associates and leaders, yet the market for talent will become increasingly competitive. Shifting demographic trends will result in fewer students, fewer graduates and fewer people entering the workforce in the Western world in the next 10 years. The supply of talent for key functional and leadership positions is decreasing, and a talent gap is clearly visible for some professions and geographies engineers in Germany, for example. Recruitment is increasingly regional or global in specialized fields such as clinical development, biosciences, chemistry and information technology.

Emerging markets are expected to be a driving force in global growth, but in countries like Russia and China there is a limited pool of executives with the training and international experience needed to work successfully in a global organization like Novartis. Moreover, younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles. Geographic mobility is expected to decrease, and talent 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 legislative proposals in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel.

We face intense competition for an increasingly limited pool of qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. As a result, we may be unable to attract and retain qualified individuals in sufficient numbers, which would have an adverse effect on our business, financial condition and results of operations.

#### Environmental liabilities may adversely impact our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on us to remediate contaminated sites. While we have set aside substantial provisions for worldwide environmental liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts for which we have provided in the Group consolidated financial statements. If we are required to further increase our provisions for environmental liabilities in the future, or if we fail to properly manage 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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## Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

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

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

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

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

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

#### Climate change and earthquakes 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 risks as a result of these weather patterns. These risks include: (i) a potential reduction in ice and snow cover, potentially leading to a reduced availability of cooling water for our facilities in Europe; (ii) potential changes in precipitation extremes and droughts, potentially leading to flooding, which may affect sites in Europe, China and India, while drought may affect sites in the UK, India and Australia; (iii) potentially rising sea levels, which could affect sites in Singapore, Shanghai and Bangladesh; (iv) potential tropical cyclones, which could affect operations in the US and Asia; (v) potential changes in the availability of natural resources, which could affect, among other things, the availability of biological ingredients for our products, and the generation of electricity in countries heavily dependent upon hydro-electricity. As a result of these and other potential impacts of climate change on the environment, our business, financial condition and results of operations could be put at risk.

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

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locations around the world. In the event of a major earthquake, we could experience business interruptions, destruction of facilities and loss of life, all of which could have a material adverse effect on our business, financial condition and results of operations.

#### Risks Related To Our ADSs

The price of our ADSs 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) trade on the New York Stock Exchange (NYSE) in US dollars. Since the shares underlying the ADSs are listed in Switzerland on the SIX Swiss Exchange (SIX) and trade in Swiss francs, the value of the ADSs 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 ADSs. If the value of the Swiss franc decreases against the US dollar, the price at which our ADSs trade may and the value of the US dollar equivalent of any dividend will decrease accordingly.

#### Holders of ADSs may not be able to exercise preemptive rights attached to shares underlying ADSs.

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 ADSs may not be able to exercise the preemptive rights attached to the shares underlying their ADSs 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 ADS holders of the preemptive rights associated with the shares underlying their ADSs. 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 ADS 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 ADS holders in Novartis would be diluted and, if the depositary allowed rights to lapse, holders of ADSs would not realize any value from the preemptive rights.

### 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

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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 31."

#### **Important Corporate Developments 2010-January 2013**

#### 2013

January

Novartis announces that, at his own wish, Novartis AG Chairman of the Board of Directors Daniel Vasella, M.D. 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 proposes 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 intends to elect Joerg Reinhardt as Chairman of the Board of Directors as from August 1, 2013. From February 22, 2013 until the designation of a new Chairman, the Board of Directors intends to elect its current Vice-Chairman, Ulrich Lehner, Ph.D., as Chairman of the Board of Directors.

#### 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.

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 \$50,000 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.

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2011

December

Following the seventh interim review of data from the ALTITUDE study with *Tekturna/Rasilez* (aliskiren), Novartis decided to terminate the trial based on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the study. The DMC concluded that patients were unlikely to benefit from treatment on top of standard anti-hypertensive medicines, and identified higher adverse events in patients receiving *Tekturna/Rasilez* in addition to standard of care in the trial. Novartis has written to healthcare professionals worldwide recommending that hypertensive patients with diabetes should not be treated with *Tekturna/Rasilez*, or combination products containing aliskiren, if they are also receiving an angiotensin-converting enzyme (ACE) inhibitors or an angiotensin receptor blocker (ARB). As an additional precautionary measure, Novartis has ceased promotion of *Tekturna/Rasilez*-based products for use in combination with an ACE or ARB. A reassessment of the future sales potential of *Tekturna/Rasilez* in light of the ALTITUDE results has led to an exceptional charge of approximately \$900 million (of which approximately \$800 million are non-cash) to be recognized in the fourth quarter of 2011. The charge comprises impairments to intangible and manufacturing assets and excess inventory together with trial wind down and other exit costs. The accounting charge is triggered by lower sales expectations and does not seek to anticipate the results of our ongoing discussions with health authorities concerning *Tekturna/Rasilez*.

We voluntarily suspended operations and shipments from the OTC Division facility located at Lincoln, Nebraska. This action was taken to accelerate maintenance and other improvement activities at the site. Subsequently, in January 2012, we voluntarily recalled certain OTC Division products, as well as an Animal Health Division product that were produced at the Lincoln facility. We took a charge of \$115 million related to the temporary suspension of production at the facility.

Novartis discontinues development of PRT128 for acute coronary syndrome and chronic coronary heart disease, and SMC021 for osteoporosis and osteoarthritis, resulting in intangible asset and other impairment charges of approximately \$160 million.

October

Novartis discontinues development of AGO178 for major depressive disorder, resulting in an intangible asset impairment charge of \$87 million.

April

Following the acquisition of the remaining non-controlling interest in Alcon, Inc., on April 8, an Extraordinary General Meeting of Novartis shareholders approved the merger of Alcon, Inc. into Novartis, creating the global leader in eye care. As a result, the Alcon Division became the newest division in our strategically diversified healthcare portfolio. In order to complete the transaction, the Extraordinary General Meeting authorized the Board of Directors of Novartis to issue 108 million new shares which, together with 57 million shares held in treasury, were used to fund part of the merger consideration.

Novartis sells global rights to Elidel®, a medicine to treat atopic dermatitis, for \$420 million to Meda.

March

Novartis completes acquisition of majority stake in Zhejiang Tianyuan vaccines company in China. The total amount paid for the 85% interest was \$194 million, excluding \$39 million of cash acquired.

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January

Novartis announces agreement to acquire Genoptix, Inc. in an all cash tender offer. The acquisition, which was completed in March, of 100% of the shares of Genoptix totaled \$458 million, excluding the \$24 million of cash acquired. Genoptix laboratory service offerings are expected to provide a strategic fit with our diagnostics activities, and to complement our internal capabilities aimed at improving health outcomes by advancing individualized treatment programs.

#### 2010

December

Novartis announces \$500 million investment over the next five years in healthcare in Russia, including for the construction of a new Novartis manufacturing plant in St. Petersburg, and the expansion of research and development collaborations and public health alliances. Construction of the manufacturing plant began in June 2011.

Novartis announces that it has entered into a definitive agreement with Alcon to merge Alcon into Novartis, subject to certain approvals and conditions, which when completed would cause Alcon to be 100% owned by Novartis and enable Alcon to become a new division of Novartis focused on eye care. Novartis also announced the reactivation of its share buyback program.

November

Novartis discontinues development of ASA404 for non-small cell lung cancer, resulting in an intangible asset impairment charge of approximately \$120 million.

October

Novartis discontinues development of two investigational compounds: albinterferon alfa-2b for hepatitis C and *Mycograb* for invasive candidiasis, resulting in impairment and other charges of approximately \$584 million.

September

Novartis Pharmaceuticals Corporation (NPC), a US subsidiary of Novartis AG, agrees to settle civil and criminal investigations by the US Government regarding *Trileptal* and five other products. As part of the settlement, NPC agreed to plead guilty to one misdemeanor, and to pay criminal fines and civil penalties totaling \$422.5 million. NPC also entered into a five-year Corporate Integrity Agreement, which will require it to implement additional compliance-related measures.

Novartis sells US rights to the overactive bladder treatment Enablex® to Warner Chilcott for \$400 million in cash.

August

Novartis completes 77% majority ownership of Alcon adding new growth platform in eye care to its leading healthcare portfolio.

July

NPC agrees to settle gender discrimination claims associated with class action brought on behalf of female members of sales force for payment of \$152.5 million to eligible class members, and commitment to implement comprehensive programs designed to ensure that all members of its sales force are treated fairly. The court approved the settlement in November.

April

Sandoz announces the acquisition of Oriel Therapeutics. The transaction closed in June, gaining rights to a portfolio of respiratory products targeting asthma and COPD.

March

Novartis successfully completes a \$5.0 billion bond market transaction in three tranches.

February

Novartis gains exclusive rights to DEB025, an antiviral agent in Phase IIb development as potential first-in-class hepatitis C therapy.

January

Novartis announces its intention to gain full ownership of Alcon by first completing the April 2008 agreement with Nestlé S.A. to acquire a 77% majority stake in Alcon, and subsequently entering into an all-share direct merger with Alcon for the remaining 23% minority stake.

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

#### 4.B Business Overview

#### **OVERVIEW**

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio includes innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products.

The Group's wholly-owned businesses are organized into six global operating divisions, and we report our results in the following five segments:

Pharmaceuticals: Innovative patent-protected prescription medicines

Alcon: Surgical, ophthalmic pharmaceutical and vision care products

Sandoz: Generic pharmaceuticals

Vaccines and Diagnostics: Human vaccines and blood-testing diagnostics

Consumer Health: OTC (over-the-counter medicines) and Animal Health

Novartis is the only healthcare company globally with leading positions in each of these areas. To maintain our competitive positioning across these growing segments of the healthcare industry, we place a strong focus on innovating to meet the evolving needs of patients around the world, growing our presence in new and emerging markets, and enhancing our productivity to invest for the future and increase returns to shareholders.

Novartis achieved net sales of \$56.7 billion in 2012, while net income amounted to \$9.6 billion. Research & Development expenditure in 2012 amounted to \$9.3 billion (\$9.1 billion excluding impairment and amortization charges). Of the Group's total net sales, \$13.9 billion, or 24%, came from Emerging Growth Markets, and \$42.8 billion, or 76%, came from Established Markets. Emerging Growth Markets are all markets other than the Established Markets of the US, Canada, Japan, Australia, New Zealand and Western Europe.

Headquartered in Basel, Switzerland, our Group companies employed approximately 128,000 full-time equivalent associates as of December 31, 2012, and sell products in approximately 140 countries around the world.

On January 23, 2012, we announced that, at his own wish, Novartis AG Chairman of the Board of Directors Daniel Vasella, M.D. 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 proposes 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 intends to elect Joerg Reinhardt as Chairman of the Board of Directors as from August 1, 2013. From February 22, 2013 until the designation of a new Chairman, the Board of Directors intends to elect its current Vice-Chairman, Ulrich Lehner, Ph.D., as Chairman of the Board of Directors.

Joerg Reinhardt joined our predecessor company, Sandoz, in 1982 and held positions of increasing responsibility for Novartis, including serving as Head of Pharmaceutical Development, Head of the Vaccines and Diagnostics Division and, commencing in 2008, Group Chief Operating Officer, a position he held until January 31, 2010. Since August 15, 2010, Joerg Reinhardt has been Chairman of the Board of Management of Bayer HealthCare AG and Chairman of the Bayer HealthCare Executive Committee. If elected to the Board of Directors of Novartis, he would step down from these positions at Bayer prior to August 1, 2013.

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#### **Pharmaceuticals Division**

Pharmaceuticals researches, develops, manufactures, distributes and sells patented prescription medicines and is organized in the following business franchises: Oncology; Primary Care, consisting of Primary Care medicines and Established Medicines; and Specialty Care, consisting of Ophthalmology, Neuroscience, Integrated Hospital Care, and Critical Care medicines. Novartis Oncology is organized as a business unit, responsible for the global development and marketing of oncology products. In 2012, the Pharmaceuticals Division accounted for \$32.2 billion, or 56.7%, of Group net sales, and for \$9.6 billion, or 80.3%, of Group operating income (excluding Corporate income and expense, net).

#### **Alcon Division**

Our Alcon Division researches, develops, manufactures, distributes and sells eye care products and technologies to serve the full life cycle of eye care needs. Alcon offers a broad range of products to treat many eye diseases and conditions, and is organized into three businesses: Surgical, Ophthalmic Pharmaceuticals and Vision Care. The Surgical portfolio includes technologies and devices for cataract, retinal, glaucoma and refractive surgery, as well as intraocular lenses to treat cataracts and refractive errors, like presbyopia and astigmatism. Alcon also provides viscoelastics, surgical solutions, surgical packs, and other disposable products for cataract and vitreoretinal surgery. In Ophthalmic Pharmaceuticals, the portfolio covers treatment options for elevated intraocular pressure caused by glaucoma, anti-infectives to aid in the treatment of bacterial infections and bacterial conjunctivitis, and ophthalmic solutions to treat inflammation and pain associated with ocular surgery. The pharmaceutical product portfolio also includes eye and nasal allergy treatments, as well as over-the-counter dry eye relief and ocular vitamins. Daily disposable, monthly replacement, and color-enhancing contact lenses, as well as a complete line of contact lens care products including multi-purpose and hydrogen-peroxide based solutions, rewetting drops, and daily protein removers, comprise the portfolio in Vision Care. In 2012, Alcon accounted for \$10.2 billion, or 18.0%, of Group net sales, and for \$1.5 billion, or 12.3%, of Group operating income (excluding Corporate income and expense, net).

#### **Sandoz Division**

Our Sandoz Division develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical and biotechnological active substances, which are not protected by valid and enforceable third-party patents. Sandoz has activities in Retail Generics, Anti-Infectives, Biopharmaceuticals & Oncology Injectables. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and sells biotechnology manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market. Sandoz Ophthalmics, which was formed through the integration of Alcon's generic division Falcon, develops, manufactures and markets generic ophthalmic and otic products. In addition, Sandoz expanded its presence in Respiratory through the acquisition of Oriel Therapeutics in 2010, and expanded its presence in Dermatology through the acquisition of specialty dermatology company Fougera Pharmaceuticals in 2012. In 2012, Sandoz accounted for \$8.7 billion, or 15.4%, of Group net sales, and for \$1.1 billion, or 9.1%, of Group operating income (excluding Corporate income and expense, net).

### **Vaccines and Diagnostics Division**

Our Vaccines and Diagnostics Division researches, develops, manufactures, distributes and sells preventive human vaccines and novel blood-screening diagnostic tools, which help protect the world's

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blood supply by preventing the spread of infectious diseases. In 2012, the Vaccines and Diagnostics Division accounted for \$1.9 billion, or 3.3%, of Group net sales, and an operating loss of \$250 million.

#### **Consumer Health**

Consumer Health consists of two Divisions: Over-the-Counter (OTC) and Animal Health. Each has its own research, development, manufacturing, distribution and selling capabilities, but neither is material enough to the Group to be separately disclosed as a segment. OTC offers readily available consumer medicine, and Animal Health provides veterinary products for farm and companion animals. In 2012, Consumer Health accounted for \$3.7 billion, or 6.6%, of Group net sales, and for \$48 million, or 0.4%, of Group operating income (excluding Corporate income and expense, net).

#### **PHARMACEUTICALS**

#### Overview

Our Pharmaceuticals Division is a world leader in offering innovation-driven, patent-protected medicines to patients and physicians.

The Pharmaceuticals Division researches, develops, manufactures, distributes and sells patented pharmaceuticals in the following therapeutic areas:

Oncolog	gy
Primary	Care
	Primary Care medicines
	Established Medicines
Specialt	y Care
	Ophthalmology
	Neuroscience
	Integrated Hospital Care
	Critical Care

The Pharmaceuticals Division is organized into global business franchises responsible for the commercialization of various products as well as Novartis Oncology, a business unit responsible for the global development and commercialization of oncology products.

The Pharmaceuticals Division is the largest contributor among the six divisions of Novartis and reported consolidated net sales of \$32.2 billion in 2012, which represented 56.7% of the Group's net sales.

The division is made up of approximately 80 affiliated companies which together employed 61,268 full-time equivalent associates as of December 31, 2012, and sell products in approximately 140 countries. The product portfolio of the Pharmaceuticals Division includes more than 50 key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 130 potential new products and new indications or new formulations for existing products in various stages of clinical development.

## **Pharmaceuticals Division Products**

The following table and summaries describe certain key marketed products in our Pharmaceuticals Division. While we intend to sell our marketed products throughout the world, not all products and indications are currently available in every country. Compounds and new indications in development are

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subject to required regulatory approvals and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. It may not be possible to obtain regulatory approval for any or all of the new compounds and new indications referred to in this Form 20-F in any country or in every country. In addition, for some of our products, we are required to conduct post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the products under special conditions. See "Regulation" for further information on the approval process. Some of the products listed below have lost patent protection or are otherwise subject to generic competition. Others are subject to patent challenges by potential generic competitors. See below and "Intellectual Property" for further information on the patent status of our Pharmaceuticals Division's products.

## **Key Marketed Products**

Business franchise Oncology	Product Afinitor/Votubia	Common name everolimus	Indication <sup>(1)</sup> Advanced renal cell carcinoma after failure of treatment with VEGF-targeted therapy Advanced pancreatic neuroendocrine tumors SEGA associated with tuberous sclerosis Renal angiomyolipoma associated with tuberous sclerosis Advanced breast cancer in post-menopausal HR+/HER2- women in combination with exemestane, after failure of anastrozole or letrozole	Formulation Tablet Dispersible tablets for oral suspension
	Exjade	deferasirox	Chronic iron overload due to blood transfusions	Dispersible tablet for oral suspension
	Femara	letrozole	Hormone receptor positive early breast cancer in postmenopausal women following surgery (upfront adjuvant therapy) Early breast cancer in post-menopausal women following standard tamoxifen therapy (extended adjuvant therapy) Advanced breast cancer in post-menopausal women (both as first- and second-line therapies)	Tablet
	Gleevec/ Glivec	imatinib mesylate/imatinib	Certain forms of chronic myeloid leukemia Certain forms of gastrointestinal stromal tumors Certain forms of acute lymphoblastic leukemia Dermatofibrosarcoma protuberans Hypereosinophilic syndrome Aggressive systemic mastocytosis Myelodysplastic/myeloproliferative diseases	Tablet Capsules
	Jakavi	ruxolitnib	Disease-related splenomegaly or symptoms in adult patients with primary myelopfibrosis (also known as chronic idiopathic myelobfibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis	Tablet
	Sandostatin LAR & Sandostatin SC	octreotide acetate for injectable suspension & octreotide acetate	Acromegaly Symptom control for certain forms of neuroendocrine tumors Delay of tumor progression in patients with midgut tumors	Vial Ampoule/pre-filled syringe
	Signifor	Pasireotide	Cushing's disease	Ampoule/syringe
	Tasigna	nilotinib	Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including <i>Gleevec/Glivec</i> First line chronic myeloid leukemia	Capsule
	Zometa	zoledronic acid	Skeletal-related events from bone metastases (cancer that has spread to the bones) Hypercalcemia of malignancy	Vial Ready-to-use

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Business franchise (1) Indications vary	<b>Product</b> by country.	Common name	Indication <sup>(1)</sup>	Formulation
Primary Care Primary Care	Amturnide	aliskiren, amlodipine besylate and hydrochlorothiazide	Hypertension	Tablet
	Arcapta Neohaler/ Onbrez Breezhaler	Indacaterol	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Diovan	valsartan	Hypertension Heart failure Post-myocardial infarction	Tablets/capsules/oral solution
	Diovan HCT/ Co-Diovan	valsartan and hydrochlorothiazide	Hypertension	Tablet
	Eucreas	vildagliptin and metformin	Type 2 diabetes	Tablet
	Exforge	valsartan and amlodipine besylate	Hypertension	Tablet
	Exforge HCT	valsartan, amlodipine besylate and hydrochlorothiazide	Hypertension	Tablet
	Galvus	vildagliptin	Type 2 diabetes	Tablet
	Seebri Breezhaler	glycopyrronium	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Tekamlo/Rasilamlo	aliskiren and amlodipine besylate	Hypertension	Tablet
	Tekturna/Rasilez	aliskiren	Hypertension	Tablet
	Tekturna HCT/Rasilez HCT	aliskiren and hydrochlorothiazide	Hypertension	Tablet
Established Medicines	Clozaril/ Leponex	clozapine	Treatment-resistant schizophrenia Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and psychotic disorders	Tablet
	Coartem/ Riamet	artemether and lumefantrine	Plasmodium falciparum malaria or mixed infections that include Plasmodium falciparum Standby emergency malaria treatment	Tablet Dispersible tablet for oral suspension
	Focalin & Focalin XR	dexmethylphenidate HCl & dexmethylphenidate extended release	Attention deficit hyperactivity disorder	Tablet Capsule
	Foradil	formoterol	Asthma Chronic obstructive pulmonary disease	Aerolizer (capsules) Aerosol
	Lamisil	terbinafine (terbinafine	Fungal infection of the skin and nails caused by dermatophyte fungi Tinea capitis	Tablet Cream

hydrochloride)

Fungal infections of the skin for the treatment of tinea corporis, tinea cruris, tinea pedis and yeast infections of the skin caused by the genus

DermGel Solution Spray

Candida

Onychomycosis of the toenail or fingernail due to dermatophytes

(1) Indications vary by country.

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Business franchise	Product Lescol/ Lescol XL	Common name fluvastatin sodium	Indication <sup>(1)</sup> Hypercholesterolemia and mixed dyslipidemia in adults Secondary prevention of major adverse cardiac events Slowing the progression of atherosclerosis Heterozygous familial hypercholesterolemia in children and adolescents	Formulation Capsule Tablet
	Cibacen	benazepril hydrochloride	Hypertension Adjunct therapy in congestive heart failure Progressive chronic renal insufficiency	Tablet
	Miacalcin/ Miacalcic	salmon calcitonin	Osteoporosis in patients for whom alternative treatments are not suitable Bone pain associated with osteolysis and/or osteopenia Paget's disease of the bone only in patients who do not respond to alternative treatments or for whom such treatments are not suitable Neurodystrophic disorders (synonymous with algodystrophy or Sudeck's disease) Hypercalcemia	Nasal spray Ampoule & multi-dose Vial for injection or infusion
	Reclast/ Aclasta	zoledronic acid 5 mg	Treatment of osteoporosis in postmenopausal women Treatment of osteoporosis in men Treatment and prevention of glucocorticoid-induced osteoporosis Prevention of postmenopausal osteoporosis Treatment of Paget's disease of the bone	Intravenous infusion
	Ritalin	methylphenidate HCl	Attention deficit hyperactivity disorder and narcolepsy	Tablet
	Ritalin LA	methylphenidate HCl modified release	Attention deficit hyperactivity disorder	Capsule
	Tegretol	carbamazepine	Epilepsy Pain associated with trigeminal neuralgia Acute mania and bipolar affective disorders	Tablet Chewable tablet Oral suspension Suppository
	Trileptal	oxcarbazepine	Epilepsy	Tablet Oral suspension
	Vivelle Dot/ Estradot	estradiol hemihydrate	Estrogen replacement therapy for the treatment of the symptoms of natural or surgically induced menopause Prevention of postmenopausal osteoporosis	Transdermal patch
	Voltaren/Cataflam	diclofenac sodium/potassium/resinate/free acid	Inflammatory and degenerative forms of rheumatism Post-traumatic and post-operative pain, inflammation and swelling Painful and/or inflammatory conditions such as migraine, ear, nose and throat, or dysmenorrhoea	Tablet Capsule Oral drop Ampoule for injection Suppository Gel Powder for oral solution Transdermal patch

<sup>(1)</sup> Indications vary by country.

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Business franchise Specialty Care	Product	Common name	Indication <sup>(1)</sup>	Formulation
Ophthalmology	Lucentis	ranibizumab	Wet age-related macular degeneration Visual impairment due to diabetic macular edema Visual impairment due to macular edema secondary to retinal vein occlusion	Intravitreal injection
Neuroscience	Comtan	entacapone	Parkinson's disease	Tablet
	Exelon & Exelon Patch	rivastigmine tartrate & rivastigmine transdermal system	Mild-to-moderate Alzheimer's disease dementia Dementia associated with Parkinson's disease	Capsule Oral solution Transdermal patch
	Extavia	interferon beta-1b	Relapsing remitting and/or relapsing forms of multiple sclerosis in adult patients	Subcutaneous injection
	Fanapt	iloperidone	Schizophrenia	Tablet
	Gilenya	fingolimod	Relapsing forms of multiple sclerosis	Capsule
	Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet
Integrated Hospital Care	Cubicin	daptomycin	Complicated skin and skin structure infections caused by Gram-positive susceptible isolates Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by susceptible isolates	Powder for solution, injection or infusion
	Ilaris	canakinumab	Cryopyrin-associated periodic syndrome	Lyophilized powder for reconstitution for subcutaneous injection
	Myfortic	mycophenolic acid (as mycophenolate sodium)	prophylaxis of organ rejection in patients receiving allogeneic renal transplants	Gastro-resistant tablet
	Neoral/Sandimmune	cyclosporine, USP Modified	Prevention of rejection following certain organ transplantation Non-transplantation autoimmune conditions such as severe psoriasis and severe rheumatoid arthritis	Capsule Oral solution Intravenous (Sandimmune)
	Simulect	basiliximab	Prevention of acute organ rejection in de novo renal transplantation	Vial for injection or infusion
	Tyzeka/Sebivo	telbivudine	Chronic hepatitis B	Tablet Oral solution
	Zortress/Certican	everolimus	Prevention of organ rejection (heart, liver and kidney)	Tablet Dispersible tablet
Critical Care	TOBI/TOBI Podhaler	tobramycin	Pseudomonas aeruginosa infection in cystic fibrosis	Nebulizer solution/Inhalation powder

Xolair

omalizumab

Allergic asthma

Lyophilized powder for reconstitution and liquid formulation in pre-filled syringes as subcutaneous injection

(1) Indications vary by country and/or formulation.

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#### **Selected Leading Products**

Oncology

Gleevec/Glivec (imatinib mesylate/imatinib mesylate) is a kinase inhibitor approved to treat patients with metastatic and/or unresectable KIT+ gastrointestinal stromal tumors (GIST), as an adjuvant treatment for certain adult patients following resection of KIT+ GIST, and as a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). First launched in 2001, Gleevec/Glivec is available in more than 110 countries. Gleevec/Glivec is also approved in the US, EU and Japan to treat Philadelphia chromosome-positive acute lymphoblastic leukemia, a rapidly progressive form of leukemia. We have filed marketing authorization applications with the EMA and FDA for the additional indication of pediatric Ph+ ALL. Gleevec/Glivec is also approved in the US and EU to treat dermatofibrosarcoma protuberans, a rare solid tumor; hypereosinophilic syndrome and myelodysplastic/myeloproliferative diseases and other rare blood disorders. In the US, Gleevec is approved for aggressive systemic mastocytosis. Gleevec/Glivec has received approvals as a post-surgery (adjuvant setting) therapy for certain KIT+ GIST patients in more than 60 countries, including the US and EU. In February 2012, the FDA approved an update to the Gleevec label recommending three years of treatment for adult patients following complete gross resection of KIT+ GIST, based on data demonstrating a survival benefit with three years of treatment relative to one year. Also in 2012, the European Commission approved an update to the Glivec label to include the three year data.

Tasigna (nilotinib) is a signal transduction inhibitor of the tyrosine kinase activity of Bcr-Abl, KIT and the PDGF-receptor. Since its launch in 2007, Tasigna is approved in more than 95 countries to treat patients with Ph+ CML in the chronic and/or accelerated phase who are resistant or intolerant to existing treatment, such as Gleevec/Glivec. It is also approved in more than 70 markets, including the US, EU member states, Switzerland and Japan, to treat newly diagnosed patients in the chronic phase. Results from the global, randomized Phase III trial called ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients), a head-to-head comparison against Gleevec/Glivec, showed that Tasigna produced faster and deeper responses than Gleevec/Glivec in adult patients with newly diagnosed Ph+ CML. In the ENESTnd four-year follow-up, the difference in the rates of deep molecular response continued to be significantly higher for Tasigna than for Glivec, with the difference in favor of Tasigna increasing over time. In addition, a sub-analysis showed that more than three times as many patients achieved early molecular response (reduction in BCR-ABL transcript levels to ≤10% at months three and six) with *Tasigna* as first-line therapy instead of *Glivec*. ENESTcmr is the first randomized trial in patients with Ph+ CML to investigate the impact of switching adult patients with residual molecular disease to Tasigna after a minimum of two years on treatment with Gleevec/Glivec, showed that 23% of the patients who switched to Tasigna achieved undetectable levels of Bcr-Abl within 12 months compared to 11% who continued on Gleevec/Glivec. Two-year results from ENESTcmr showed that switching to Tasigna led to deeper molecular responses in patients who still had evidence of residual disease after long-term therapy with Glivec. More than twice as many patients treated with Tasigna continued to achieve undetectable BCR-ABL than patients treated with Glivec. The difference between groups by 24 months was statistically significant (22.1% vs. 8.7%; p=0.0087) and that difference had doubled since the 12-month analysis. In addition to the ongoing studies in Ph+ CML, trials are also underway examining the use of *Tasigna* in patients with c-Kit mutated, advanced melanoma.

Zometa (zoledronic acid for injection/zoledronic acid 4 mg) is a leading treatment to reduce or delay skeletal-related events, including pathologic fracture, spinal cord compression, and/or requirement of radiation therapy or surgery to bone, in patients with bone metastases (cancer that has spread to the bones) from solid tumors and multiple myeloma. First approved in the US in 2001 for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of calcium),

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Zometa is approved in more than 100 countries for this indication as well as for the treatment of patients with multiple myeloma and patients with bone metastasis from solid malignancies, including prostate, breast and lung cancer. Zoledronic acid, the active ingredient in Zometa, is also available under the trade names Reclast/Aclasta for use in non-oncology indications. Zometa is expected to face generic challenges in 2013 when the patent on its active ingredient, zoledronic acid, will expire in the US and other major markets. See " Intellectual Property" below for further information on the patent status of Zometa.

Femara (letrozole) is a once-daily oral aromatase inhibitor for the treatment of early stage or advanced breast cancer in postmenopausal women. Femara was first launched in 1996 and is currently available in more than 90 countries. Femara is approved in the US, EU member states and other countries in the adjuvant, extended adjuvant and neoadjuvant settings for early stage breast cancer. Femara is also approved in the US and other countries as adjuvant therapy for locally advanced breast cancer and for advanced breast cancer following anti-estrogen therapy. Femara is approved as neo-adjuvant (pre-operative) therapy for early stage breast cancer in a limited number of countries. In Japan, Femara is approved for the treatment of all hormone receptor-positive breast cancer in postmenopausal women. Femara has faced generic competition since 2011 when the patent on its active ingredient, letrozole, expired in the US and major countries in Europe. See

"Intellectual Property" below for further information on the patent status of Femara.

Sandostatin SC/Sandostatin LAR (octreotide acetate/octreotide acetate for injectable suspension) is indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of pituitary growth hormone in adults. Sandostatin is also indicated for the treatment of patients with certain symptoms associated with carcinoid tumors and other types of gastrointestinal and pancreatic neuroendocrine tumors. Additionally, Sandostatin LAR is approved in more than 39 countries for the delay of tumor progression in patients with midgut carcinoid tumors. A total of 26 countries have also approved a new presentation of Sandostatin LAR, which includes a new diluent, safety needle and vial adapter improving the mixing and administration, with additional filings underway. Sandostatin was first launched in 1988 and is approved in more than 100 countries. Sandostatin SC faces worldwide generic competition. Formulation patents covering Sandostatin LAR expired in July 2010 in all countries except the US, where the expiration of formulation patents begins from the end of 2014. The expiration of the last formulation patent in the US will be in January 2017. There are currently no equivalent versions of Sandostatin LAR approved in any markets.

*Exjade* (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients over two years of age. Patients with congenital and acquired chronic anemia, such as thalassemia, sickle cell disease and myelodysplastic syndromes, require transfusions, which puts them at risk of iron overload. *Exjade* was first approved in 2005 and is now approved in more than 100 countries, including the US, EU member states and Japan.

Afinitor/Votubia (everolimus), is an oral inhibitor of the mTOR pathway. Afinitor is approved in more than 80 countries and regions including the US, EU member states and Japan for advanced renal cell carcinoma following vascular endothelial growth factor-targeted therapy. Afinitor is also approved in nearly 50 countries, including the US, EU and Japan for the treatment of advanced pancreatic neuroendocrine tumors. In July 2012, Afinitor was approved in the US for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+/HER2-breast cancer) in combination with exemestane after failure of treatment with letrozole or anastrozole, and in the EU for the treatment of hormone receptor-positive (HR+), HER2/neu-negative (HER2-) advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor. Afinitor is now approved in 46 countries for advanced HR+/HER2- breast cancer. Everolimus is also approved in more than 40 countries

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including in the US as *Afinitor* and in the EU as *Votubia* to treat patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates or amenable for surgery. In August 2012, the FDA granted an accelerated approval for a label update for *Afinitor* in TSC-SEGA to include Phase III data from the EXIST-1 trial, and also approved a new formulation of the product, *Afinitor Disperz* tablets for oral suspension, for use in this patient population. This dispersible formulation was also approved in Japan in December 2012. In addition, everolimus is also approved in the US as *Afinitor* and in the EU as *Votubia* for the treatment of adult patients with renal angiomyolipomas and TSC who do not require immediate surgery. Everolimus, the active ingredient in *Afinitor*, is also available under the trade names *Zortress/Certican* for use in transplantation, and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Jakavi (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thromboycythemia myelfibrosis Jakavi was approved by Health Canada in June 2012 and by the European Commission in August 2012. In the US, ruxolitinib is marketed by Incyte as Jakafi® and was approved by the FDA in November 2011. In two-year follow-up data from the COMFORT-I and COMFORT-II Phase III studies in myelofibrosis, Jakavi treatment resulted in sustained reductions in spleen size, a hallmark of myelofibrosis, while also improving quality of life and extending overall survival compared to placebo or the best available therapy.

Signifor (pasireotide) is a multireceptor targeting somatostatin analog. Signifor was approved in the EU in April 2012 and in the US in December 2012 for the treatment of adult patients with Cushing's disease, an endocrine disorder caused by excessive cortisol, for whom surgery is not an option or has failed. Signifor is the first approved pituitary-targeted medicine for Cushing's disease.

#### Primary Care

#### Primary Care

Diovan (valsartan), together with Diovan HCT/Co-Diovan (valsartan and hydrochlorothiazide), is the top-selling anti-hypertensive medication worldwide (IMS September 2012; 59 countries audited). Diovan is the only agent in its class approved to treat all of the following: high blood pressure (including children 6 to 18 years), high-risk heart attack survivors and patients with heart failure. First launched in 1996, Diovan is available in more than 120 countries for treating high blood pressure, in more than 90 countries for heart failure, and in more than 70 countries for heart attack survivors. First launched in 1997, Diovan HCT/Co-Diovan is approved in over 100 countries worldwide. In July 2008, the FDA approved Diovan HCT for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In 2009, Co-Diovan was approved for treatment of high blood pressure in Japan. In September 2010, all 27 EU member states locally approved Diovan for use in children aged 6 to 18 years. In 2012, the Japanese Ministry of Health, Labor and Welfare (MHLW) approved Diovan for the treatment of pediatric hypertension in children age 6 years or older. This approval marks the first time an angiotensin II receptor blocker (ARB) has been approved for the treatment of pediatric hypertension in children age 6 years or older in Japan. Diovan has faced generic competition in recent years when the patent on its active ingredient, valsartan, expired in the major countries of the EU in 2011, and in the US in 2012. Patent expiration will follow in Japan in 2013 for Diovan and 2016 for Co-Diovan (including patent term extensions). See "Intellectual Property" below for further information on the patent status of Diovan.

*Exforge* (valsartan and amlodipine besylate) is a single-pill combination of the ARB *Diovan* and the calcium channel blocker amlodipine besylate. First approved for the treatment of high blood pressure in Switzerland in 2006, and in the US and EU in 2007, it is now available in more than 100

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countries. In 2008, the FDA approved *Exforge* for the first-line treatment of hypertension in patients likely to need multiple drugs to achieve their blood pressure goals. In January 2010, *Exforge* was approved in Japan and also launched in China. *Exforge HCT* (valsartan, amlodipine besylate and hydrochlorothiazide) is a single pill combining three widely prescribed high blood pressure treatments: an ARB (valsartan), calcium channel blocker (amlodipine) and a diuretic (hydrochlorothiazide). *Exforge HCT* was approved in the EU and the US in 2009, and is now available in more than 60 countries.

Galvus (vildagliptin), an oral DPP-4 inhibitor, and Eucreas, a single-pill combination of vildagliptin and metformin, are indicated for the for the treatment of type 2 diabetes. The products were first approved in 2008. Galvus is currently approved in more than 100 countries, including EU member states, Latin America, Asia-Pacific and Japan. Eucreas was the first single-pill combining a DPP-4 inhibitor and metformin to be launched in Europe and is currently approved in more than 85 countries. In 2012, Galvus received EU approval for expanded use as a second-line monotherapy for type 2 diabetes patients who cannot take meformin. In addition, in 2012, the European Commission approved the use of Galvus and Eucreas in combination with other diabetes treatments. The first new approval was for the use of vildagliptin in combination with insulin, with or without metformin, for patients with type 2 diabetes when diet, exercise and a stable dose of insulin do not result in glycemic control. The second approval was for the use of vildagliptin in triple combination with metformin and a sulphonylurea for the treatment of type 2 diabetes when diet and exercise plus dual therapy with these two agents do not provide adequate glycemic control.

Arcapta Neohaler/Onbrez Breezhaler (indacaterol) is a long-acting beta<sub>2</sub>-agonist administered in a single-dose dry powder inhaler indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Once-daily Onbrez Breezhaler was first approved in the EU in November 2009 at two dose strengths, 150 mcg and 300 mcg. It is now approved in more than 90 countries. In July 2011, the FDA approved a 75 mcg once-daily dose of indacaterol under its US trade name, Arcapta Neohaler, and Japanese regulatory authorities approved Onbrez Inhalation Capsules in a 150 mcg once-daily dose. In 2012, Onbrez Breezhaler 150 mcg was also approved in China. It was the first inhaled COPD product administered to patients via the low resistance Breezhaler device.

Seebri Breezhaler (glycopyrronium), a long-acting muscarinic antagonist (LAMA), received its first regulatory approvals in September 2012. Seebri Breezhaler (glycopyrronium) 44 mcg delivered dose (equivalent to 50 mcg glycopyrronium measured dose per capsule) received approval in the EU as a once-daily inhaled maintenance bronchodilator treatment to relieve symptoms for adult patients with COPD. In Japan, the MHLW approved once-daily Seebri (glycopyrronium) Inhalation Capsules 50 mcg glycopyrronium administered through the Breezhaler device as an inhaled maintenance bronchodilator treatment for the relief of various symptoms due to airway obstructive disease in chronic obstructive pulmonary disease (chronic bronchitis and emphysema). A Phase III clinical trial program for glycopyrronium has been agreed with the FDA. Filing in the US is expected in 2014. Seebri is the second inhaled COPD product delivered to patients via the low resistance Breezhaler device.

Tekturna/Rasilez (aliskiren) is a treatment for high blood pressure, and the first and only approved direct renin inhibitor. Tekturna/Rasilez was approved in the US and EU in 2007, and is now approved in more than 100 countries. The product is known as Tekturna in the US and Rasilez in the rest of the world. There are various Tekturna/Rasilez single-pill combination products approved in various countries, including Tekturna/Rasilez combined with the diuretic hydrochlorothiazide, sold as Tekturna HCT in the US and Rasilez HCT in the EU, and Tekturna/Rasilez combined with the calcium channel blocker amlodipine, which is sold as Tekamlo in the US and Rasilamlo in the EU. A triple combination of these drugs is available in the US, as well, combining aliskiren, amlodipine and hydrochlorothiazide under the brand name Amturnide. In December 2011,

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Novartis announced the termination of the ALTITUDE study which was investigating *Tekturna/Rasilez* in a high-risk population of patients with type 2 diabetes and renal impairment. This action was taken on the recommendation of the independent Data Monitoring Committee overseeing the trial, after the likelihood of showing a benefit of *Tekturna/Rasilez* treatment in this population was seen to be extremely low, and a higher risk of adverse events was identified in patients receiving *Tekturna/Rasilez* than those on placebo. In 2012, the *Tekturna/Rasilez* product information was updated in the EU, US, Japan and other countries to include the addition of a contraindication against the combined use of aliskiren with an ACE inhibitor or an ARB in patients with diabetes, and a contraindication/warning against the combined use of aliskiren with an ACE inhibitor or an ARB in patients with renal impairment. In August 2012, the European Commission renewed the Rasilez Marketing Authorization. Novartis voluntarily ceased marketing *Valturna*, a single pill combination containing aliskiren and the ARB valsartan, in the US as of July 2012. ALTITUDE end of treatment results confirmed the preliminary findings and were presented in August at the European Society of Cardiology Congress 2012. Patient safety is the highest priority for Novartis and the Company is sharing the end of treatment results with health authorities as required. Aliskiren products remain available for appropriate patients.

#### Established Medicines

Reclast/Aclasta (zoledronic acid 5 mg) is the first and only once-yearly bisphosphonate infusion for the treatment of different forms of osteoporosis, and for the treatment of Paget's disease of the bone in men and women. Sold as Reclast in the US and Aclasta in the rest of the world, the product is approved in more than 100 countries including the US, EU member states and Canada, and is the only bisphosphonate approved to reduce the incidence of fractures at all three key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. The Reclast/Aclasta label was expanded in the EU and US to include the reduction in the incidence of clinical fractures after a low trauma hip fracture. The EU has also approved Aclasta for the treatment of osteoporosis in men at increased risk of fracture and for the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in men at increased risk of fracture. Reclast is also approved in the US as a treatment to increase bone mass in men with osteoporosis, the prevention and treatment of glucocorticoid-induced osteoporosis in men and women, as well as for the prevention of osteoporosis in postmenopausal women. Zoledronic acid, the active ingredient in Reclast/Aclasta, is also approved in a number of countries in a different dosage under the trade name Zometa for certain oncology indications. Reclast/Aclasta is expected to face generic challenges in 2013 when the patent on its active ingredient, zoledronic acid, will expire in the US and other major markets. See "Intellectual Property" below for further information on the patent status of Reclast/Aclasta.

Voltaren/Cataflam (diclofenac sodium/potassium/resinate/free acid) is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions. Voltaren/Cataflam was first launched in 1973 and is available in more than 140 countries. This product, which is subject to generic competition, is marketed by the Pharmaceuticals Division in a wide variety of dosage forms, including tablets, drops, suppositories, ampoules and topical therapy. In addition, in various countries, our OTC Division markets low-dose oral forms and the topical therapy of Voltaren as over-the-counter products.

Ritalin, Ritalin LA, Focalin and Focalin XR (methylphenidate HCl, methylphenidate HCl extended release, dexmethylphenidate HCl and dexmethylphenidate HCl extended release) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and Focalin XR is additionally indicated for adults. Ritalin and Ritalin LA are also indicated for narcolepsy. Ritalin was first marketed during the 1950s and is available in over 70 countries. Ritalin LA is available in over 30 countries. Focalin comprises the active d-isomer of methylphenidate and therefore requires half the dose of Ritalin. Focalin XR is now approved in Switzerland. Focalin and Focalin XR are available in the US. Immediate-release Focalin is subject to generic competition.

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Specialty Care

Ophthalmology

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors (VEGF). It is the only anti-VEGF therapy licensed in many countries for three ocular indications: wet age-related macular degeneration (wet AMD), visual impairment due to diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO). Lucentis is approved in more than 100 countries to treat patients with wet AMD. Lucentis is approved for the treatment of visual impairment due to DME and macular edema secondary to RVO in more than 80 countries. Since its launch in 2007, there are more than 1.5 million patient-treatment years of exposure for Lucentis. Lucentis is developed in collaboration with Genentech, which holds the rights to the product in the US.

#### Neuroscience

Gilenya (fingolimod) is the first in a new class of multiple sclerosis (MS) therapies called sphingosine 1-phosphate receptor modulators and the first oral therapy approved to treat relapsing-remitting MS (RRMS). In the US, Gilenya is indicated for relapsing forms of MS. In the EU, Gilenya is indicated for adult patients with highly active RRMS defined as either high disease activity despite treatment with beta interferon, or rapidly evolving severe RRMS. In a pivotal Phase III study, Gilenya demonstrated superior efficacy to interferon beta-1a IM, a commonly prescribed treatment, reducing relapses by 52% at one year. A two-year, placebo-controlled pivotal study also showed that Gilenya also significantly reduced the risk of disability progression compared to placebo. Gilenya has a well-studied safety and tolerability profile with over 2,600 MS clinical trial patients included in the FDA regulatory review. Some patients are in their seventh year of treatment. As of November 2012, approximately 56,000 patients have been treated in clinical trials and in a post-marketing setting, and there are currently approximately 62,000 patient years of exposure. In April 2012, following completion of their safety reviews, the FDA and the EMA both confirmed the positive benefit-risk profile of Gilenya when used in accordance with the respective updated Product Information, which provide further guidance to healthcare professionals regarding the initiation of Gilenya treatment. Both updated Product Informations include additional requirements (blood pressure monitoring and ECG) during the existing six-hour observation period following the first dose, and more specific guidance on patient selection parameters to aid in the identification of patients suitable for Gilenya treatment. In particular situations, it is recommended that monitoring following the first dose be extended. Gilenya is currently approved in over 65 countries around the world. Gilenya is licensed from Mitsubishi Tanabe Pharma Corporation.

Exelon (rivastigmine tartrate) and Exelon Patch (rivastigmine transdermal system) are cholinesterase inhibitors indicated for the treatment of Alzheimer's disease (AD) dementia and Parkinson's disease (PD) dementia. Exelon capsules have been available since 1997 to treat mild to moderate AD dementia in more than 90 countries. In 2006, Exelon became the only cholinesterase inhibitor to be approved for mild to moderate PD dementia in addition to AD in both the US and EU. Exelon Patch was approved in 2007 in the US and EU and has been approved for the treatment of mild-to-moderate AD in more than 80 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. The once-daily Exelon Patch has shown comparable efficacy to the highest recommended doses of Exelon capsules, with significant improvement in cognition and overall functioning compared to placebo. Exelon capsules are now subject to generic competition in several markets, including the US. In August 2012, the FDA approved a higher dose of Exelon Patch for the treatment of people with mild to moderate AD and mild to moderate PD dementia. In November 2012, CHMP issued a positive opinion for the approval of the higher dose of Exelon Patch for the treatment of patients with mild to moderately severe Alzheimer's disease.

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Extavia (interferon beta-1b) is an injectable disease modifying therapy for relapsing forms of multiple sclerosis (MS), as well as for patients who have had a single episode/demyelinating event and MRI findings consistent with MS in both the US and EU and for secondary progressive MS with active disease, evidenced by relapses in the EU. It is the Novartis brand of interferon beta-1b, a product also marketed by Bayer Healthcare Pharmaceuticals Inc. under the brand name Betaseron® in the US and by Bayer Schering Pharma under the brand name Betaferon® in the EU. Bayer Schering supplies the product to Novartis under an agreement reached in 2007. Extavia was first approved in the EU in 2008 and since 2009 has been launched in more than 35 countries, including the US.

Comtan and Stalevo (entacapone and carbidopa, levodopa and entacapone) are indicated for the treatment of Parkinson's disease. Stalevo (carbidopa, levodopa and entacapone) is indicated for certain Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations, known as "wearing off". Stalevo was approved in the US and EU in 2003, and is available from Novartis in more than 50 countries. Comtan (entacapone) is also indicated for the treatment of Parkinson's disease patients who experience end-of-dose wearing off and is marketed in approximately 50 countries. Both products are marketed by Novartis under a licensing agreement with the Orion Corporation.

Integrated Hospital Care

Zortress/Certican (everolimus) is an oral inhibitor of the mTOR pathway, indicated for certain transplant indications. Zortress/Certican the most-extensively studied immunosuppressant in solid organ transplantation with more than 10,000 transplant recipients enrolled in Novartis-sponsored clinical trials worldwide. Under the trade name Certican, it is approved in more than 90 countries to prevent organ rejection for renal and heart transplant patients, and in addition, is approved in the EU, Chile, Philippines and Argentina to prevent organ rejection for liver transplant patients. In the US, under the trade name Zortress, the drug is approved for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant. Everolimus is also available from Novartis in different dosage strengths and for different uses in non-transplant patient populations under the brand names Afinitor and Votubia. It is also exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

*Ilaris* (canakinumab) is a fully human monoclonal antibody that selectively binds and neutralizes interleukin-1β (IL-1β), a pro-inflammatory cytokine. Since 2009, *Ilaris* has been approved in over 60 countries for the treatment of children and adults suffering from cryopyrin associated periodic syndrome, a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life threatening amyloidosis. In January 2013, the CHMP issued an opinion supporting the approval in the EU of *Ilaris* for the treatment of acute gouty arthritis in patients who cannot be managed with standard of care. Approval by the European Commission is expected in the first half of 2013.

Neoral (cyclosporine, USP Modified) is an immunosuppressant to prevent organ rejection following a kidney, liver, or heart transplant. Neoral is also approved for use in lung transplant in many countries outside of the US. This micro-emulsion formulation of cyclosporine is also indicated for treating selected autoimmune disorders such as psoriasis and rheumatoid arthritis. First launched in 1995, Neoral is marketed in approximately 100 countries. This product is subject to generic competition.

*Myfortic* (enteric-coated formulation of mycophenolate sodium) is approved in more than 90 countries for the prevention of acute rejection of kidney allografts, and is indicated in combination with cyclosporine and corticosteroids. *Myfortic* was first approved in the US in 2004 and in the EU in 2003.

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Critical Care

Xolair (omalizumab) is the first humanized monoclonal antibody approved for the treatment of moderate to severe persistent allergic asthma in the US in adolescents (aged 12 and above) and adults. It is approved for severe persistent allergic asthma in the EU in children (aged six and above), adolescents, and adults. Xolair is approved in more than 90 countries, including the US since 2003 and the EU since 2005. A liquid formulation of Xolair in pre-filled syringes has been launched in most European countries. Novartis co-promotes Xolair with Genentech/Roche in the US and shares a portion of operating income, but does not record any US sales. Novartis records all sales of Xolair outside the US.

TOBI Podhaler (tobramycin inhalation powder) is an inhaled dry powder formulation of the antibiotic tobramycin, delivered using a simple and portable patient-friendly device that reduces administration time by 72% relative to TOBI (tobramycin nebulizer solution), with comparable efficacy and safety. TOBI Podhaler has been approved in the EU since July 2011 and is now available in most European countries as well as in Canada and some Latin American countries. It is indicated for the management of cystic fibrosis patients aged six years and older with Pseudomonas aeruginosa infection in their lungs, whose lung function is within a certain range. In the US, Novartis has been working to address feedback from the FDA, which issued a complete response letter to the NDA for TOBI Podhaler (the provisional US trade name) in October 2012. An FDA advisory committee previously voted 13 to 1 that there was adequate evidence of efficacy and safety to support its use in the proposed indication.

#### **Compounds in Development**

The traditional model of development comprises three phases, which are defined as follows:

**Phase I:** First clinical trials of a new compound, generally performed in a small number of healthy human volunteers, to assess the clinical safety, tolerability as well as metabolic and pharmacologic properties of the compound.

**Phase II:** Clinical studies that are performed on patients with the targeted disease, to continue the Phase I safety assessment in a larger group, to assess the efficacy of the drug in the patient population, and to determine the appropriate doses for further testing.

**Phase III:** Large scale clinical studies to establish the safety and effectiveness of the drug for regulatory approval for indicated uses. Phase III trials may also be used to compare a new drug against a current standard of care in order to evaluate the overall risk/benefit relationship of the new drug.

Though we use this traditional model as a platform, we have tailored the process to be simpler, more flexible and efficient. Our development paradigm consists of two parts: Exploratory development and Confirmatory development. Exploratory development consists of clinical "proof of concept" (PoC) studies, which are small clinical trials (typically 5-15 patients) that combine elements of traditional Phase I/II testing. These customized trials are designed to give early insights into issues such as safety, efficacy and toxicity for a drug in a given indication. Once a positive proof of concept has been established, the drug moves to the Confirmatory development stage. Confirmatory development has elements of traditional Phase II/III testing and includes trials aimed at confirming the safety and efficacy of the drug in the given indication leading up to submission of a dossier to health authorities for approval. Like traditional Phase III testing, this stage can also include trials which compare the drug to the current standard of care for the disease, in order to evaluate the drug's overall risk/benefit profile.

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The following table and paragraph summaries provide an overview of the key projects currently in the Confirmatory development stage within our Pharmaceuticals Division, including projects seeking to develop potential uses of new molecular entities, as well as potential additional indications or new formulations for already marketed products.

A reference to a project being in registration means that it has been submitted to a health authority for marketing approval.

## **Selected Development Projects**

Project/Product ACZ885	Common name canakinumab	Mechanism of action Anti IL-1β monoclonal antibody	Potential indication/ Disease area Gouty arthritis	Business franchise Integrated Hospital Care	Formulation/ Route of administration Subcutaneous injection	Year Project Entered Current Development Phase EU: 2010 US: 2011	Planned filing dates/Current phase EU (registration) US (registration)
			Systemic juvenile idiopathic arthritis	Integrated Hospital Care		2012	EU (registration) US (registration)
			Diabetes mellitus	Critical Care		2009	≥ 2017/II
			Secondary prevention of cardiovascular events	Critical Care		2011	2016/III
AFQ056	mavoglurant	Metabotropic glutamate receptor 5 antagonist	Fragile X syndrome	Neuroscience	Oral	2010	2014/III
			L-dopa induced dyskinesia in Parkinson's disease			2006	2015/II
AIN457	secukinumab	Anti IL-17 monoclonal antibody	Psoriasis	Integrated Hospital Care	Lyophilized powder in vial; Intravenous infusion, subcutaneous injection	2011	2013/III
			Arthritic conditions (Rheumatoid arthritis, Ankylosing Spondylitis, Psoriatic Arthritis)			2011	2014/III
			Multiple sclerosis	Neuroscience		2009	≥2017/II
ATI355	TBD	Anti NOGO-A mAb	Spinal cord injury	Neuroscience	Intrathecal spinal injection	2006	≥2017/I
AUY922	TBD	ATP-competitive nongeldanamycin	Solid tumors	Oncology	Intravenous	2009	≥2017/II

## inhibitor of HSP90

BAF3	12	siponimod	Sphingosine-1- phosphate (S1P) receptor modulator	Multiple sclerosis	Neuroscience	Tablet	2012	≥2017/III
BCT1	97	TBD	Anti-inflammatory agent	Chronic obstructive pulmonary disease	Primary Care	Oral	2011	≥2017/II
BEZ2	35	TBD	P13K/mTOR inhibitor	Solid tumors	Oncology	Oral	2010	≥2017/II
BGS6	549	TBD	Aromatase inhibitor	Obese hypogonadotropic hypogonadism	Critical Care	Oral	2010	≥2017/II
BKM	120	TBD	P13K inhibitor	Breast cancer	Oncology	Oral	2011	2015/III
				Solid tumors			2011	≥2017/I
BYL7	791	TBD	P13K inhibitor	Solid tumors	Oncology	Tablet	2010	≥2017/I
BYM	338	TBD	Inhibitor of Activin receptor Type II	Sporadic Inclusion Body Myositis	Integrated Hospital Care	Intravenous infusion	2012	2016/II
CAD	106	TBD	Beta-amyloid-protein immunotherapy	Alzheimer's disease	Neuroscience	Subcutaneous, intramuscular injection	2008	≥2017/II

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Project/Product CTL019	Common name TBD	Mechanism of action CD19-targeted chimeric antigen receptor (CAR) T-cell immunotherapy	Potential indication/ Disease area Leukemia	Business franchise Oncology	Formulation/ Route of administration Intravenous	Year Project Entered Current Development Phase 2012	Planned filing dates/Current phase 2016/II
DEB025	alisporivir	Cyclophilin inhibitor	Chronic hepatitis C	Integrated Hospital Care	Oral	2011	≥2017/III
Exjade	deferasirox	Iron chelator	Non-transfusion dependent thalassemia	Oncology	Oral	EU 2012 US 2011	EU (approved) US (registration)
Gilenya	fingolimod	Sphingosine-1- phosphate receptor modulator	Chronic inflammatory demyelinating poly-radiculoneuropathy	Neuroscience	Oral	2012	2016/II
Jakavi	ruxolitinib	Janus kinase inhibitor	Polycythemia vera	Oncology	Oral	2010	2014/III
KAE609	TBD	Unknown	Malaria	Established Medicines	Oral	2012	≥2017/II
LBH589	panobinostat	Histone deactelylase inhibitor	Relapsed or relapsed-and-refractory Multiple Myeloma	Oncology	Oral	2009	2013/III
			Hematological cancers			2009	≥2017/II
LCI699	TBD	Aldosterone synthase inhibitor	Cushing's disease	Oncology	Oral	2011	2016/II
LCQ908	TBD	Diacylglycerol acyl transferase-1 inhibitor	Familial chylomicronemia syndrome	Critical Care	Tablet	2012	2014/III
LCZ696	TBD	Angiotensin receptor-blocker/ neprilysin Inhibitor	Chronic heart failure	Critical Care	Oral	2009	2014/III
			Hypertension	Primary Care		2012	2013/III
LDE225	TBD	Smoothed receptor inhibitor	Advanced basal cell carcinoma	Oncology	Oral	2011	2014/II
			Solid tumors			2011	2016/II
LDK378	TBD	ALK inhibitor	Non-small cell lung cancer	Oncology	Oral	2012	2014/II
LFF571	TBD	Bacterial elongation factor Tu (EFTu) inhibitor	Clostridium difficile infection	Integrated Hospital Care	Oral	2010	≥2017/II

LGX818	TBD	RAF inhibitor	Melanoma	Oncology	Oral	2012	≥2017/I
LIK066	TBD	SGLT 1 / 2 inhibitor	Type II diabetes	Primary care	Oral	2011	≥2017/II
Lucentis	ranibizumab	Anti-VEGF monoclonal antibody fragment	Choroidal neovascularization secondary to pathological myopia	Ophthalmology	Intravitreal injection	2012	EU (registration)
			Choroidal neovascularization and Macular edema	Ophthalmology	Intravitreal injection	2010	2016/II
MEK162	TBD	MEK inhibitor	Melanoma	Oncology	Oral	2011	2015/II
NVA237 (Seebri)	glycopyrronium	Long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Primary Care	Inhalation	2012	EU (approved) US (2014/III)
PKC412	midostaurin	Signal transduction inhibitor	Aggressive systemic mastocytosis	Oncology	Oral	2008	2015/II
			Acute myeloid leukemia			2008	2015/III
QAW039	TBD	Anti-inflammatory agent	Asthma	Primary Care	Oral	2010	≥2017/II
QGE031	TBD	High affinity anti-IgE monoclonal antibody	Allergic diseases	Primary Care	Subcutaneous injection	2012	≥ 2017/II
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Project/Product QMF149	Common name indacaterol and mometasone furoate	Mechanism of action Long-acting beta2- agonist and inhaled corticosteroid	Potential indication/ Disease area Chronic obstructive pulmonary disease	Business franchise Primary Care	Formulation/ Route of administration Inhalation	Year Project Entered Current Development Phase 2007	Planned filing dates/Current phase 2015/II
			Asthma			2007	2015/II
QVA149	indacaterol and glycopyrronium	Long-acting beta2- agonist and long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Primary Care	Inhalation	2012	EU (registration) US (2014/III)
RAD001 (Afinitor/ Votubia)	everolimus	mTOR inhibitor	Breast cancer HER2-over-expressing, 1st line	Oncology	Tablet	2009	2014/III
			Breast cancer HER2-over- expressing 2nd/3rd line			2009	2013/III
			Hepatocellular carcinoma			2010	2013/III
			Non-functioning GI/Lung, NET			2012	2015/III
			Diffuse large B-cell lymphoma			2009	2015/III
RLX030	serelaxin	Recombinant form of human relaxin-2 hormone	Acute heart failure	Critical Care	Intravenous infusion	EU 2012 US 2009	EU (registration) US 2013/III
Signifor LAR	pasireotide	Somatostatin analogue	Acromegaly	Oncology	Long-acting release: monthly intramuscular injection	2008	2013/III
			Cushing's disease			2011	2015/III
Tasigna	nilotinib	Signal transduction inhibitor	metastatic melanoma with c-KIT mutation	Oncology	Capsule	2011	2014/III
Tekturna	aliskiren	Direct renin inhibitor	Reduction of CV death/hospitalizations in chronic heart failure patients	Critical Care	Tablet	2009	2015/III
TOBI Podhaler	tobramycin inhalation powder	Aminoglycoside antibiotic	Pseudomonas aeruginosa infection in cystic fibrosis patients	Critical Care	Dry powder inhalation	EU: 2012 US: 2011	EU (approved) US (registration)

TKI258	dovitinib lactate	VEGFR1-3, FGFR 1-3, PDGFR angiogenesis inhibitor	Renal cell carcinoma	Oncology	Oral	2011	2013/III
			Solid tumors			2009	2016/II
Xolair	omalizumab	Anti-IgE monoclonal antibody	Chronic idiopathic urticaria	Integrated Hospital Care	Subcutaneous injection	2011	2013/III
Zortress/Certican	everolimus	mTOR inhibitor	Prevention of organ rejection liver	Integrated Hospital Care	Oral	EU: 2012 US: 2011	EU (approved) US (registration)
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#### Key Compounds in Development (select products in Phases II, III and Registration)

ACZ885 (canakinumab) was filed in the EU in December 2010 and in the US in February 2011 for the treatment of acute attacks in gouty arthritis (GA). In the US, Novartis continues to work with the FDA to determine the next steps for ACZ885 in GA, following a Complete Response letter received in August 2011 with a request by the Agency for additional clinical data to evaluate the benefit risk profile in refractory patients. In Europe, the CHMP issued an opinion supporting the approval in the EU of *Ilaris* for the treatment of acute gouty arthritis in patients who cannot be managed with standard of care. Approval by the European Commission is expected in the first half of 2013. In systemic juvenile idiopathic arthritis (SJIA), results from two pivotal Phase III trials showed ACZ885 provided significant symptom relief and helped to substantially reduce, and potentially even fully eliminate, oral steroid use in SJIA patients. Worldwide regulatory submissions took place in 2012. Phase II data of ACZ885 in TNF-receptor associated periodic syndrome (TRAPS) and Familial Mediterranean Fever (FMF) showed substantial symptom relief in these two rare periodic fever syndromes. ACZ885 is also being investigated for the secondary prevention of cardiovascular events. A Phase II study conducted by the independent Type 1 Diabetes TrialNet group showed that ACZ885 did not provide an efficacy benefit compared to placebo after 12 months of treatment in newly diagnosed patients with Type 1 diabetes. There was no significant difference in the number and severity of adverse events between the ACZ885 and placebo groups.

AFQ056 (mavoglurant) is a metabotropic glutamate receptor 5 (mGluR5) antagonist in Phase III development for the treatment of Parkinson's disease levodopa- induced dyskinesia. No therapy has previously been approved for this condition, which represents a complication after dopamine-replacement therapy in Parkinson's patients and which is characterized by a variety of hyperkinetic movements. Phase II studies in adult and adolescent patients with Fragile X syndrome started in the fourth quarter of 2010 and the second quarter of 2011 respectively. Fragile X syndrome is the most frequent inherited form of mental retardation. AFQ056 aims to improve the associated behavioral symptoms.

AIN457 (secukinumab) is a fully human monoclonal antibody selectively inhibiting interleukin-17A (IL-17A), a key pro-inflammatory cytokine. Proof-of-concept and Phase II studies in moderate-to-severe plaque psoriasis and arthritic conditions (psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis) have suggested that AIN457 may provide a new mechanism of action for the treatment of immune-mediated diseases. All core pivotal trials for AIN457 in moderate-to-severe plaque psoriasis are on track and Phase III data are expected in 2013, with regulatory submissions anticipated to follow in the same year. Phase II studies are also ongoing in other areas, including multiple sclerosis.

BAF312 is an oral, second-generation sphingosine 1-phosphate receptor modulator in Phase II development for relapsing-remitting multiple sclerosis. BAF312 binds selectively to the sphingosine 1-phosphate receptor subtypes 1 and 5, and has a relatively fast washout. The results from the BOLD study, an adaptive dose-ranging Phase II study, were presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) congress in October 2011. These results showed that BAF312 effectively suppresses MRI lesion activity in Relapsing-Remitting Multiple Sclerosis with a reduction of 80% of combined unique active MRI lesions vs placebo at three months. BAF312 entered Phase III development in Secondary Progressive MS in 2012.

BKM120 is an oral selective pan-PI3k inhibitor. The PI3K/AKT/mTOR pathway is an important intracellular signaling network that regulates cellular metabolism, proliferation and survival. Abnormal activation of the PI3K/AKT/mTOR pathway has been identified as an important step in the initiation and maintenance of tumors and a key regulator of angiogenesis and upregulated metabolic activities in tumor cells. BKM120 has shown significant cell growth inhibition and induction of apoptosis in a variety of tumor cell lines as well as in animal models. BKM120 is currently being investigated in clinical trials in advanced solid tumors in combination with other agents, including 2 phase III trials in hormone receptor positive advanced breast cancer.

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DEB025 (alisporivir), a cyclophilin inhibitor, licensed from Debiopharm and being studied for the treatment of hepatitis C, has been placed on a partial clinical hold by the FDA. Accordingly, all treatment with DEB025 is currently stopped in clinical trials. The decision to place the clinical trials on partial clinical hold comes as a result of a small number of cases of pancreatitis reported in clinical trial patients being treated with DEB025 in combination with peginterferon alpha and ribavirin, including one fatal case. Novartis is working closely with the FDA to resolve their questions.

*Gilenya* (fingolimod) is a sphingosine 1-phosphate receptor modulator approved for the treatment for relapsing forms of MS. A Phase II/III study of *Gilenya* in patients with chronic inflammatory demyelinating polyradiculoneuropathy was initiated in 2012.

Exjade (deferasirox) is an oral iron chelator in development for use in patients with non-transfusion-dependent thalassemia (NTDT). Results from the pivotal THALASSA study, the first prospective placebo-controlled study of iron chelation in NTDT patients, met the primary endpoint by demonstrating a significant dose-dependent decrease in iron burden compared to placebo. Worldwide regulatory filings are underway for Exjade as a treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes, a diverse group of genetic disorders that affect red blood cell production, causing anemia. In November 2012, the CHMP adopted a positive opinion for Exjade use in these patients, which was followed by EU approval in December.

*Jakavi* (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases in development for use in patients with polycythemia vera. The pivotal Phase III RESPONSE trial is currently enrolling patients to study ruxolitinib in patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. This trial is managed by Incyte in the US and by Novartis outside the US.

LBH589 (panobinostat) is a highly potent pan deacetylase inhibitor targeting the epigenetic regulation of multiple oncogenic pathways, with development focused on hematological disease. The LBH589 Phase III PANORAMA-1 trial of bortezomib/dexamethasone plus panobinostat or placebo in relapsed or relapsed-and-refractory multiple myeloma has completed accrual, and regulatory filings are planned for this indication in 2013.

LCQ908 is a diacylglycerol acyltransferase-1 (DGAT-1) inhibitor. DGAT-1 catalyzes the final committed step in triglyceride synthesis and is believed to play a key role in whole body energy homeostasis. Inhibition of DGAT-1 represents a novel approach to treat metabolic disease and LCQ908 is currently in Phase III development for the treatment of an orphan disease called familial chylomicronemia syndrome.

LCZ696 is a first-in-class angiotensin receptor blocker/neprilysin inhibitor, a dual-acting compound that delivers concomitant inhibition of neprilysin and blockage of the angiotensin type 1 receptor (ARB). LCZ696 entered Phase III development at the end of 2009 for the treatment of chronic heart failure in patients with reduced ejection fraction, an indication in which angiotensin converting enzyme (ACE) inhibitors are the current standard of care. The ongoing Phase III PARADIGM-HF study tests the efficacy and safety of LCZ696 compared with the ACE inhibitor enalapril on morbidity and mortality or heart failure hospitalizations. In August 2012, results from the Phase II PARAMOUNT study showed that LCZ696 is the first therapy to significantly reduce NT-proBNP, a key predictor of morbidity and mortality in patients with heart failure with preserved ejection fraction, the other common form of chronic heart failure. In 2012, LCZ696 entered Phase III development for the treatment of hypertension.

LDK378 is a potent and highly selective oral ALK inhibitor that is in development for ALK+ cancers. A first in human phase I study of LDK378 showed preliminary clinical response in ALK+ non small cell lung cancer (NSCLC), including those previously treated with crizotinib. Phase II studies further exploring the role of LDK378 are currently recruiting patients.

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*Lucentis* (ranibizumab) for the treatment of visual impairment due to choroidal neovascularization secondary to pathological myopia was submitted for regulatory approval in the EU in September 2012. In Japan, a submission for regulatory approval was filed in this indication in October 2012.

PKC412 (midostaurin) is an oral, multi-targeted, kinase inhibitor in Phase III development for treatment of patients with acute myeloid leukemia (AML) and in Phase II development for aggressive systemic mastocytosis (ASM). Filings are expected for newly diagnosed, FLT3-mutated AML and for ASM by 2014.

QMF149 is an investigational once-daily fixed-dose combination of the long-acting beta<sub>2</sub>-agonist QAB149 (indacaterol) and the corticosteroid mometasone, licensed from Merck, delivered in a single-dose dry-powder inhaler. Phase II development for asthma and COPD is currently ongoing. Filing in the EU is expected in 2015. There are no plans to initiate activities directly related to US development.

QVA149 is an investigational fixed-dose combination of the long-acting beta<sub>2</sub>-agonist QAB149 (indacaterol) and the long-acting muscarinic antagonist NVA237 (glycopyrronium), being developed as a once-daily treatment for COPD, in a single-dose dry-powder inhaler. In 2012, Novartis submitted marketing authorization applications in the EU and Japan for the treatment of adult patients with COPD. The US Phase III program for QVA149 has been agreed with the FDA, with product filing expected in the US in 2014.

RAD001 (*Afinitor/Votubia*, everolimus) is an oral inhibitor of the mTOR pathway. Phase III studies are underway in patients with breast cancer, lymphoma, hepatocellular cancer and non-functioning GI/Lung, NET.

RLX030 (serelaxin), the first in a new class of medicines, is a recombinant form of the human hormone relaxin-2, and is believed to act through multiple mechanisms on the heart, kidneys and blood vessels. Results from the Phase III RELAX-AHF study show that RLX030 improved symptoms and reduced mortality in patients with acute heart failure (AHF). Data from the study were presented at the American Heart Association congress in November 2012 and published simultaneously in *The Lancet* showing that RLX030 significantly reduced dyspnea (or shortness of breath), the most common symptom of AHF, which was the primary objective of the study based on pre-specified protocol criteria. In addition, RLX030 was associated with a 37% reduction in all-cause mortality (a safety endpoint) and in deaths due to cardiovascular causes (an additional pre-specified efficacy endpoint) at the end of six months. Based on the findings of the RELAX-AHF study, we submitted to the EU in December 2012, and plan to file in the US in the first half of 2013.

SOM230 (pasireotide) is a somatostatin analogue in development for patients with acromegaly. In the second quarter of 2012, results were presented from the Phase III trial comparing SOM230 long-acting release (LAR) against *Sandostatin LAR*. The study found that SOM230 LAR was significantly more effective at inducing full biochemical control in patients with acromegaly, a chronic hormonal disorder that occurs when excess growth hormone is produced, compared to the current standard of care, *Sandostatin LAR*. A study of SOM230 LAR versus octreotide LAR in patients with metastatic carcinoid tumors whose disease-related symptoms are inadequately controlled by somatostatin analogues was closed based on a futility analysis showing that it was unlikely to meet its primary endpoint. No new or unexpected serious adverse events were identified for SOM230 and safety was not a factor in the decision to close the study. Other studies evaluating SOM230 as a tumor control agent continue unaffected by this decision.

Tasigna (nilotinib) is being studied in patients with cKIT mutated melanoma in a trial initiated in April 2010.

*Tekturna* (aliskiren) is a direct renin inhibitor approved for the treatment of hypertension. Aliskiren is in Phase III development in chronic heart failure (the ATMOSPHERE trial). Aliskiren is expected to be submitted to health authorities for approval based on ATMOSPHERE in 2015.

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TKI258 (dovitinib) is a multi-targeted kinase inhibitor of FGFR, VEGFR and PDGFR. With a unique preclinical profile its development is focused on FGFR-driven diseases. A Phase III registration trial in renal cell carcinoma completed accrual in September 2012.

*Xolair* (omalizumab) is a humanized monoclonal antibody approved for the treatment of persistent allergic asthma. Novartis and Genentech/Roche commenced development of omalizumab in a new indication, chronic idiopathic (or spontaneous) urticaria. Phase III studies began in 2011 and results are due to be presented in 2013. Regulatory filing is planned for 2013.

Zortress/Certican (everolimus) is an mTOR inhibitor with immune/non-immune cell proliferation inhibition being developed for prevention of solid organ transplant rejection. In 2009, Phase III development was initiated in the US for an expanded kidney transplant indication of Zortress in combination with tacrolimus and corticosteroids. In October 2012, European Health Authorities approved Certican for the prophylaxis of organ rejection in adult patients receiving a liver transplant. In the EU, it is also approved for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney or heart transplant. In the US, the action date on the liver indication is expected in early 2013.

#### Projects Added To And Subtracted From The Development Table Since 2011

Project/Product AEB071	Potential indication/ Disease area Prevention of organ rejection after transplantation kidney and liver	Change Terminated	Reason Clinical results did not show sufficient therapeutic benefit over standard of care
	Psoriasis	Terminated	Clinical results did not show sufficient therapeutic benefit over standard of care
BKM120	Endometrial cancer	Now disclosed as Breast cancer, Solid tumors	
BYL791	Solid tumors	Added	
BYM338	Sporadic Inclusion Body Myositis	Added	Entered confirmatory development
CTL019	Leukemia	Added	Compound licensed from University of Pennsylvania
HCD122	Hematological malignancies	Terminated	Studies were terminated because of limited clinical efficacy
INC424	Myelofibrosis	Commercialized	Received marketing approval in EU in 2012 under the brand name <i>Jakavi</i> .

Polycythemia vera

Now disclosed under the brand name *Jakavi* 

KAE609 Malaria Added Entered confirmatory development

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Project/Product LCI699	Potential indication/ Disease area Solid tumors	Change Now disclosed as Cushing's disease	Reason
LCQ908	Metabolic diseases	Now disclosed as Familial chylomicronemia syndrome	
LDE225	Gorlin Syndrome	Terminated	
	Solid tumors	Added	
LDK378	Non small cell lung cancer	Added	Entered confirmatory development
LGT209	Hypercholesterolemia	Terminated	Competitive environment, potential delay to launch
LGX818	Melanoma	Added	Combination therapy with MEK162 study initiated
LIK066	Type II diabetes	Added	Entered confirmatory development
MEK162	Solid tumors	Now disclosed as Melanoma	
NIC002	Smoking Cessation	Terminated	Study discontinued after Phase II data suggest there is unlikely to be a clinical benefit
QGE031	Allergic diseases	Added	
QTI571	Pulmonary arterial hypertension	Terminated	US and EU filings withdrawn; additional data required for approval
RAD001 (Afinitor/Votubia)	Tuberous sclerosis complex-angiomyolipoma	Commericalized	Received marketing approval in EU and US
	Advanced ER+, HER2- breast cancer	Commercialized	Received marketing approval in EU and US
	Non-functioning GI/Lung, NET	Added	Entered confirmatory development
	Lymphoma	Now disclosed as Diffuse large B-cell lymphoma	
SOM230	Cushing's Disease	Commercialized	

Received marketing approval in EU and US under the brand name *Signifor* 

Acromegaly Now disclosed

under the brand name Signifor

LAR

Carcinoid Syndrome Terminated

Signifor LAR Cushing's disease Added Entered confirmatory development

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#### **Principal Markets**

The Pharmaceuticals Division sells products in approximately 140 countries worldwide, but net sales are generally concentrated in the US, Europe and Japan, which together accounted for 76.6% of the division's 2012 net sales. At the same time, sales from expanding "emerging growth markets" have become increasingly important to us. See "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Factors Affecting Results of Operations Fundamental Drivers Remain Strong Growth of Emerging Markets." The following table sets forth certain data relating to our principal markets in the Pharmaceuticals Division.

Pharmaceuticals	2012 Net sales to third parties			
	\$ millions	%		
United States	10,392	32.3		
Americas (except the United States)	3,089	9.7		
Europe	10,238	31.8		
Rest of the World	8,434	26.2		
Total	32,153	100.0		

	\$ millions	%
Established Markets*	24,778	77.1
Emerging Growth Markets*	7,375	22.9
Total	32,153	100.0

Many of our Pharmaceuticals Division's products are used for chronic conditions that require patients to consume the product over long periods of time, ranging from months to years. Net sales of the vast majority of our products are not subject to material changes in seasonal demand.

#### **Production**

The primary goal of our manufacturing and supply chain management program is to ensure the uninterrupted, timely and cost-effective supply of products that meet all product specifications. We manufacture our products at 6 bulk chemical and 13 pharmaceutical production facilities as well as three biotechnology sites. Bulk chemical production involves the manufacture of therapeutically active compounds, mainly by chemical synthesis or by biological processes such as fermentation. Pharmaceutical production involves the manufacture of "galenical" forms of pharmaceutical products such as tablets, capsules, liquids, ampoules, vials and creams. Major bulk chemical sites are located in Schweizerhalle, Switzerland; Grimsby, UK; Ringaskiddy, Ireland and Changshu, China. Significant pharmaceutical production facilities are located in Stein, Switzerland; Wehr, Germany; Singapore; Torre, Italy; Barbera, Spain; Suffern, New York; Sasayama, Japan and in various other locations. Our three biotechnology plants are in Huningue, France; Basel, Switzerland and Vacaville, California.

During clinical trials, which can last several years, the manufacturing process for a particular product is rationalized and refined. By the time clinical trials are completed and products are launched, the manufacturing processes have been extensively tested and are considered stable. However, improvements to these manufacturing processes may continue over time.

Raw materials for the manufacturing process are either produced in-house or purchased from a number of third-party suppliers. Where possible, our policy is to maintain multiple supply sources so that

<sup>&</sup>quot;Established Markets" are US, Canada, Western Europe, Australia, New Zealand and Japan. "Emerging Growth Markets" are all other markets.

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the business is not dependent on a single or limited number of suppliers. However, our ability to do so may at times be limited by regulatory or other requirements. We monitor market developments that could have an adverse effect on the supply of essential materials. Our suppliers of raw materials are required to comply with Novartis quality standards.

Many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may also rely on a single source of supply.

The manufacture of our products is complex and heavily regulated by governmental health authorities, which means that supply is never guaranteed. If we or our third-party suppliers fail to comply fully with regulations then there could be a product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of such events or other unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

#### **Marketing and Sales**

The Pharmaceuticals Division serves customers with 1,717 field force representatives in the US (including supervisors), and an additional 16,752 in the rest of the world, as of December 31, 2012. These trained representatives, where permitted by law, present the therapeutic risks and benefits of our products to physicians, pharmacists, hospitals, insurance groups and managed care organizations. We are seeing the increasing influence of customer groups beyond the prescribers, and Novartis is responding by adapting our business practices. In addition, in January 2012, we announced that our US affiliate, Novartis Pharmaceuticals Corporation, planned to restructure its business to strengthen its competitive position in light of the impending loss in the US of our patent on *Diovan*, and the expected impact on worldwide sales of *Tekturna/Rasilez* after the ALTITUDE study termination. This restructuring resulted in a reduction of approximately 1,630 field force positions in the US in 2012, along with an additional 330 US headquarters positions.

Although specific distribution patterns vary by country, Novartis generally sells its prescription drugs primarily to wholesale and retail drug distributors, hospitals, clinics, government agencies and managed healthcare providers.

In the US, certain products can be advertised by way of television, newspaper and magazine advertising. Novartis also pursues co-promotion/co-marketing opportunities as well as licensing and distribution agreements with other companies when legally permitted and economically attractive.

The marketplace for healthcare is evolving with the consumer becoming a more informed stakeholder in their healthcare decisions and looking for solutions to meet their changing needs. Where permitted by law, Novartis is seeking to tap into the power of the patient, delivering innovative solutions to drive loyalty and engagement.

#### Competition

The global pharmaceutical market is highly competitive, and we compete against other major international corporations which sell patented prescription pharmaceutical products, and which have substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

As is the case with other pharmaceutical companies selling patented pharmaceuticals, Novartis faces ever-increasing challenges from companies selling generic forms of our products following the expiry of patent protection, or of products which compete with our products. Generic companies may also gain entry to the market through successfully challenging our patents, but we vigorously use legally permissible

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(1)

measures to defend our patent rights from generic challenges. In addition, we also face competition from over-the-counter (OTC) products that do not require a prescription from a physician. See also "Regulation Price Controls", below.

#### **Research and Development**

We are among the leaders in the pharmaceuticals industry in terms of research and development investment. Our Pharmaceuticals Division invested the following amounts in research and development:

	2012		2011		2010(1)	
	\$ millions	Core R&D <sup>(2)</sup> \$ millions	\$ millions	Core R&D <sup>(2)</sup> \$ millions	\$ millions	Core R&D <sup>(2)</sup> \$ millions
Research and Exploratory	ΨΙΙΙΙΙΟΙΙ	финиона	Ψιπιτοπο	финиона	Ψιμιτομο	ψ IIIIIIOIIS
Development	2,584	2,530	2,676	2,625	2,368	2,311
Confirmatory Development	4,334	4,167	4,556	4,235	4,908	4,033
Total	6,918	6,697	7,232	6,860	7,276	6,344

Restated to account for the transfer of Corporate Research to the Pharmaceuticals Division

(2) Core excludes impairments, amortization and other exceptional items

Our Pharmaceuticals Division expensed \$6.9 billion (on a core basis \$6.7 billion) in research and development in 2012. This represented 21.5% (on a core basis 20.8%) of the division's total net sales. The Pharmaceuticals Division currently has 138 projects in clinical development.

Innovation is critical to long-term success in the pharmaceutical industry. In 2011, the industry's average spend of pharmaceutical companies on research and development activities was 15% of net sales, but that number is declining as many companies opt to outsource research and development, in-license products and establish option- or risk-sharing deals with other companies. On the development side, many companies are entrusting the conduct of clinical trials to contract research organizations in an effort to cut costs. At Novartis, we have historically made the discovery and development of innovative medicines that address unmet patient needs a priority, and we plan to continue to do so. Our Pharmaceuticals Division research and development investment in excess of 20% of the division's net sales in 2012, 2011 and 2010 reflects this.

Research and Exploratory Development expenditure was \$2.6 billion in 2012, practically unchanged from the 2011 amount of \$2.7 billion. In 2011, Research and Exploratory Development expenditure increased to \$2.7 billion from \$2.4 billion in 2010, reflecting our investment in scientific talent.

Confirmatory Development expenditures in 2012 decreased by 5% to \$4.3 billion as compared against 2011. This included \$0.1 billion in impairments of intangible assets in 2012 (2011: \$0.3 billion). On a core basis, Confirmatory Development expenditure remained unchanged at \$4.2 billion in 2012 and represented 13.0% of net sales as in the prior year.

Confirmatory Development expenditures in 2011 decreased by 7% to \$4.6 billion as compared against 2010. This included \$0.3 billion in impairments of intangible assets in 2011 (2010: \$0.9 billion). On a core basis, Confirmatory Development expenditure increased to \$4.2 billion in 2011 (2010: \$4.0 billion) and represented 13.0% of net sales (2010: 13.3% of net sales).

The discovery and development of a new drug is a lengthy process, usually requiring 10 to 15 years from the initial research to bringing a drug to market, including six to eight years from Phase I clinical trials to market. At each of these steps, there is a substantial risk that a compound will not meet the

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requirements to progress further. In such an event, we may be required to abandon a compound in which we have made a substantial investment.

We manage our research and development expenditures across our entire portfolio in accordance with our internal priorities. We make decisions about whether or not to proceed with development projects on a project-by-project basis. These decisions are based on the project's potential to meet a significant unmet medical need or to improve patient outcomes, the strength of the science underlying the project, and the potential of the project (subject to the risks inherent in pharmaceutical development) to generate significant positive financial results for the Company. Once a management decision has been made to proceed with the development of a particular molecule, the level of research and development investment required will be driven by many factors including the medical indications for which it is being developed; the number of indications being pursued; whether the molecule is of a chemical or biological nature; the stage of development; and the level of evidence necessary to demonstrate clinical efficacy and safety.

#### Research program

Our Research program is responsible for the discovery of new medicines. The principal goal of our research program is to discover new medicines for diseases with unmet medical need. To do this we focus our work in areas where we have sufficient scientific understanding and believe we have the potential to change the practice of medicine. This requires the hiring and retention of the best talent, a focus on fundamental disease mechanisms that are relevant across different disease areas, continuous improvement in technologies for drug discovery and potential therapies, close alliance with clinical colleagues, and the establishment of appropriate external complementary alliances.

All drug candidates are taken to the clinic via "proof-of-concept" trials to enable rapid testing of the fundamental efficacy of the drug while collecting basic information on pharmacokinetics, safety and tolerability, and adhering to the guidance for early clinical testing set forth by health authorities.

In 2003, we established the Novartis Institutes for BioMedical Research (NIBR). At NIBR's headquarters in Cambridge, Massachusetts, more than 1,700 scientists and associates conduct research into disease areas such as cardiovascular and metabolism disease, infectious disease, oncology, muscle disorders and ophthalmology. An additional 5,000 scientists and technology experts conduct research in Switzerland, UK, Italy, Singapore, China and five other US sites. Research is conducted at these sites in the areas of neuroscience, autoimmune disease, oncology, cardiovascular disease, gastrointestinal disease and respiratory disease. Research platforms such as the Center for Proteomic Chemistry are headquartered in the NIBR site in Basel, Switzerland. In addition, The Novartis Institute for Tropical Diseases, Novartis Vaccines for Global Health, the Frederich Miescher Institute, and the Genomics Institute of the Novartis Research Foundation, focus on basic genetic and genomic research as well as research into diseases of the developing world such as malaria, tuberculosis, dengue and typhoid fever.

In August 2012, Novartis and the University of Pennsylvania (Penn) announced an exclusive global research and development collaboration to develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies for the treatment of cancers. The research component of this collaboration will focus on accelerating the discovery and development of additional therapies using CAR immunotherapy. In addition, NIBR and Penn will build the Center for Advanced Cellular Therapies at Penn (CACT) on the Penn campus in Philadelphia. The CACT will be a first-of-its kind research and development center established specifically to develop and manufacture adoptive T cell immunotherapies under the research collaboration guided by scientists and clinicians from NIBR and Penn.

In June 2011, the ophthalmology disease research group at our Alcon Division joined NIBR's ophthalmology research group. Research continues to focus on the discovery and development of chemical and biological compounds for treating diseases of the eye, with a particular focus on diseases such as glaucoma and macular degeneration. The costs for these activities are allocated to Alcon.

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In April 2011, we announced that the gastrointestinal research teams based in Horsham, UK would be co-located with teams in Basel and Cambridge. In October 2011, we announced proposals that would impact our Basel-based associates working in Neuroscience, pre-clinical safety respiratory, kinase, translational medicine and siRNA research. Both announcements are part of our ongoing effort to co-locate teams, pursue new scientific directions and take advantage of outsourcing opportunities.

In October 2010, we announced that we would invest \$600 million over the next five years to build new laboratory and office space in Cambridge on an area of land close to our research facilities on Massachusetts Avenue.

#### Development program

The focus of our Development program is to determine whether new drugs are safe and effective in humans. As previously described (see "Compounds in Development"), we view the development process as generally consisting of an Exploratory phase where a "proof of concept" is established, and a Confirmatory phase where this concept is confirmed in large numbers of patients. Within this paradigm, clinical trials of drug candidates generally proceed through the traditional three phases: I, II and III. In Phase I clinical trials, a drug is usually tested with about 5 to 15 patients. The tests study the drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action. In Phase II clinical trials, the drug is tested in controlled studies of approximately 100 to 300 volunteer patients to assess the drug's effectiveness and safety, and to establish a proper dose. In Phase III clinical trials, the drug is further tested on larger numbers of volunteer patients in clinics and hospitals. In each of these phases, physicians monitor volunteer patients closely to assess the drug's safety and efficacy. The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug. See "Regulation."

At each of these phases of clinical development, our activities are managed by our Innovation Management Board (IMB). The IMB is responsible for oversight over all major aspects of our development portfolio. In particular, the IMB is responsible for the endorsement of proposals to commence the first clinical trials of a development compound, and of major project phase transitions and milestones following a positive Proof of Concept outcome, including transitions to full development and the decision to submit a drug to health authorities. The IMB is also responsible for project discontinuations, for the endorsement of overall development strategy and the endorsement of development project priorities. The IMB is chaired by the Head of Development of our Pharmaceuticals Division and has representatives from Novartis senior management, as well as experts from a variety of fields among its core members and extended membership.

#### Companion Diagnostics & Genoptix Medical Laboratory

Recent advances in biology and bioinformatics have led to a much deeper understanding of the genetic underpinnings of disease and drug targets. Novartis is working to capitalize on these scientific advances to develop innovative diagnostic tests which potentially could improve physicians' ability to optimize patient outcomes and to administer the right treatment to the right patient at the right time.

Advancing "personalized medicine" is a core to our overall drug discovery and development strategy. To further strengthen the alignment between our drug programs and our companion diagnostic development activities, in 2012 we realigned the Molecular Diagnostics function and embedded it within Oncology Global Development. Now known as Companion Diagnostics (CDx), the function is accountable for front-to-end development and manufacturing of regulated companion diagnostics and of registrational assays in pivotal clinical trials for both Oncology and GenMeds. CDx works to harness the full power of our internal capabilities and resources in an effort to develop and commercialize important new diagnostic tests to support our development products and disease areas. Additionally, CDx

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strategically works with external collaborators to leverage technologies and capabilities that fit our diagnostic requirements.

Genoptix Medical Laboratory remains within our global Pharmaceuticals Division and continues to provide comprehensive laboratory services to community-based hematologists and oncologists in the US. Our aim is to improve health outcomes for patients by advancing the ability of physicians to define and monitor individualized treatment programs.

As the number of compounds coming into development increases, streamlined and centralized management of our assays is vital to the success of our development activities. As a result, we have expanded our Clinical Trial Assay (CTA) capabilities through the creation of the CTA Center of Excellence within Genoptix. This expansion leverages the existing internal capability and expands their business potential as an end-to-end solution for managing Clinical Trial Assays across programs.

Novartis remains committed to addressing unmet medical need regardless of market size. We continue to build our broad suite of diagnostic tools and services to improve patient outcomes. Using cutting-edge technologies such as Next Generation Sequencing, we have developed a robust and expanding portfolio of molecular diagnostic programs. We aim for multiple launches over the next few years to expand on the current offerings to our patients and our customers.

#### Alliances and acquisitions

Our Pharmaceuticals Division enters into business development agreements with other pharmaceutical and biotechnology companies and with academic institutions in order to develop new products and access new markets. We license products that complement our current product line and are appropriate to our business strategy. Therapeutic area strategies have been established to focus on alliances and acquisition activities for key disease areas/indications that are expected to be growth drivers in the future. We review products and compounds we are considering licensing using the same criteria as we use for our own internally discovered drugs.

#### Regulation

The international pharmaceutical industry is highly regulated. Regulatory authorities around the world administer numerous laws and regulations regarding the testing, approval, manufacturing, importing, labeling and marketing of drugs, and also review the safety and efficacy of pharmaceutical products. In particular, extensive controls exist on the non-clinical and clinical development of pharmaceutical products. These regulatory requirements, and the implementation of them by local health authorities around the globe, are a major factor in determining whether a substance can be developed into a marketable product, and the amount of time and expense associated with that development.

Health authorities, including those in the US, EU, Switzerland and Japan, have high standards of technical evaluation. The introduction of new pharmaceutical products generally entails a lengthy approval process. Of particular importance is the requirement in all major countries that products be authorized or registered prior to marketing, and that such authorization or registration be subsequently maintained. In recent years, the registration process has required increased testing and documentation for clearance of new drugs, with a corresponding increase in the expense of product introduction.

To register a pharmaceutical product, a registration dossier containing evidence establishing the quality, safety and efficacy of the product must be submitted to regulatory authorities. Generally, a therapeutic product must be registered in each country in which it will be sold. In every country, the submission of an application to a regulatory authority does not guarantee that approval to market the product will be granted. Although the criteria for the registration of therapeutic drugs are similar in most countries, the formal structure of the necessary registration documents and the specific requirements, including risk tolerance, of the local health authorities varies significantly from country to country. It is possible that a drug can be registered and marketed in one country while the registration authority in

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another country may, prior to registration, request additional information from the pharmaceutical company or even reject the product. It is also possible that a drug may be approved for different indications in different countries.

The registration process generally takes between six months and several years, depending on the country, the quality of the data submitted, the efficiency of the registration authority's procedures and the nature of the product. Many countries provide for accelerated processing of registration applications for innovative products of particular therapeutic interest. In recent years, intensive efforts have been made among the US, the EU and Japan to harmonize registration requirements in order to achieve shorter development and registration times for medical products. However, the requirement in many countries to negotiate selling prices or reimbursement levels with government regulators can substantially extend the time until a product may finally be launched to the market.

The following provides a summary of the regulatory processes in the principal markets served by Pharmaceuticals Division affiliates:

### **United States**

In the US, applications for drug registration are submitted to and reviewed by the FDA. The FDA regulates the testing, manufacturing, labeling and approval for marketing of pharmaceutical products intended for commercialization in the US. The FDA continues to monitor the safety of pharmaceutical products after they have been approved for marketing in the US market. The pharmaceutical development and registration process is typically intensive, lengthy and rigorous. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's quality, safety and efficacy, then the company may file a New Drug Application (NDA) or biologics license application (BLA), as applicable, for the drug. The NDA or BLA must contain all the scientific information that has been gathered about the drug and typically includes information regarding the clinical experiences of patients tested in the drug's clinical trials. A Supplemental New Drug Application (sNDA) or BLA amendment must be filed for new indications for a previously approved drug.

Once an NDA or BLA is submitted, the FDA assigns reviewers from its staff in biopharmaceutics, chemistry, clinical microbiology, pharmacology/toxicology, and statistics staff. After a complete review, these content experts then provide written evaluations of the NDA or BLA. These recommendations are consolidated and are used by the Senior FDA staff in its final evaluation of the NDA/BLA. Based on that final evaluation, FDA then provides to the NDA or BLA's sponsor an approval, or a "complete response" letter if the NDA or BLA application is not approved. If not approved, the letter will state the specific deficiencies in the NDA or BLA which need to be addressed. The sponsor must then submit an adequate response to the deficiencies in order to restart the review procedure.

Once the FDA has approved an NDA, BLA, sNDA or BLA amendment, the company can make the new drug available for physicians to prescribe. The drug owner must submit periodic reports to the FDA, including any cases of adverse reactions. For some medications, the FDA requires additional post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the product under special conditions.

Throughout the life cycle of a product, the FDA also requires compliance with standards relating to good laboratory, clinical, manufacturing and promotional practices.

### European Union

In the EU, there are three main procedures for application for authorization to market pharmaceutical products in the EU Member States, the Centralized Procedure, the Mutual Recognition Procedure and the Decentralized Procedure. It is also possible to obtain a national authorization for products intended for commercialization in a single EU member state only, or for additional indications for licensed products.

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Under the Centralized Procedure, applications are made to the European Medicines Agency (EMA) for an authorization which is valid for the European Community. The Centralized Procedure is mandatory for all biotechnology products and for new chemical entities in cancer, neurodegenerative disorders, diabetes and AIDS, autoimmune diseases or other immune dysfunctions and optional for other new chemical entities or innovative medicinal products or in the interest of public health. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's quality, safety and efficacy, then the company may submit an application to the EMA. The EMA then receives and validates the application, and appoints a Rapporteur and Co-Rapporteur to review it. The entire review cycle must be completed within 210 days, although there is a "clock stop" at day 120, to allow the company to respond to questions set forth in the Rapporteur and Co-Rapporteur's Assessment Report. When the company's complete response is received by the EMA, the clock restarts on day 121. If there are further aspects of the dossier requiring clarification, the EMA will then request an Oral Explanation on day 180, in which the sponsor must appear before the EMA's Scientific Committee (the CHMP) to provide the requested additional information. On day 210, the CHMP will then take a vote to recommend the approval or non-approval of the application. The final decision under this Centralized Procedure is an EU Community decision which is applicable to all Member States. This decision occurs on average 60 days after a positive CHMP recommendation.

Under the Mutual Recognition Procedure (MRP), the company first obtains a marketing authorization from a single EU member state, called the Reference Member State (RMS). In the Decentralized Procedure (DCP) the application is done simultaneously in selected or all Member States if a medicinal product has not yet been authorized in a Member State. During the DCP, the RMS drafts an Assessment Report within 120 days. Within an additional 90 days the Concerned Member States (CMS) review the application and can issue objections or requests for additional information. On Day 90, each CMS must be assured that the product is safe and effective, and that it will cause no risks to the public health. Once an agreement has been reached, each Member State grants national marketing authorizations for the product.

After the Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMA (if approval was granted under the Centralized Procedure) or to the National Health Authorities (if approval was granted under the DCP or the MRP). In addition, several Pharmacovigilance measures must be implemented and monitored including Adverse Event collection, evaluation and expedited reporting and implementation as well as up-date of Risk Management Plans.

European Marketing Authorizations have an initial duration of five years. After this time, the Marketing Authorization may be renewed by the competent authority on the basis of re-evaluation of the risk/benefit balance. Once renewed the Marketing Authorization is valid for an unlimited period. Any Marketing Authorization which is not followed within three years of its granting by the actual placing on the market of the corresponding medicinal product shall cease to be valid.

### Japan

In Japan, applications for new products are made through the Pharmaceutical and Medical Devices Agency (PMDA). Once an NDA is submitted, a review team is formed consisting of specialized officials of the PMDA, including chemistry/manufacturing, non-clinical, clinical and biostatistics. While a team evaluation is carried out, a data reliability survey and Good Clinical Practice/Good Laboratory Practice inspection are carried out by the Office of Conformity Audit of the PMDA. Team evaluation results are passed to the PMDA's external experts who then report back to the PMDA. After a further team evaluation, a report is provided to the Ministry of Health, Labor and Welfare (MHLW), which makes a final determination for approval and refers this to the Council on Drugs and Foods Sanitation which then advises the MHLW on final approvability. Marketing and distribution approvals require a review to determine whether or not the product in the application is suitable as a drug to be manufactured and distributed by a person who has obtained a manufacturing and distribution business license for the type of

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drug concerned and confirmation that the product has been manufactured in a plant compliant with Good Manufacturing Practices.

Once the MHLW has approved the application, the company can make the new drug available for physicians to prescribe. After that, the MHLW has listed its national health insurance price within 60 days (or 90 days) from the approval, and physicians can obtain reimbursement. For some medications, the MHLW requires additional post-approval studies (Phase IV) to evaluate safety, effects and/or to gather information on the use of the product under special conditions. The MHLW also requires the drug's sponsor to submit periodic safety update reports. Within three months from the specified re-examination period, which is designated at the time of the approval of the application for the new product, the company must submit a re-examination application to enable the drug's safety and efficacy to be reassessed against approved labeling by the PMDA.

### **Price Controls**

In most of the markets where we operate, the prices of pharmaceutical products are subject to both direct and indirect price controls and to drug reimbursement programs with varying price control mechanisms. Due to increasing political pressure and governmental budget constraints, we expect these mechanisms to continue to remain robust and to perhaps even be strengthened and to have a negative influence on the prices we are able to charge for our products.

Direct efforts to control prices.

*United States.* In the US, as a result of health care reform legislation enacted in 2010 and the recurring focus on deficit reduction, there is a significant risk of continued actions to control prices. Specifically, one proposal that has been repeatedly advanced would impose a government-mandated pricing formula on both patented and generic medications provided through the Medicare prescription drug benefit (Medicare Part D). As to health care reform, there is a newly created entity, the Independent Payment Advisory Board, which has been granted unprecedented authority to implement broad actions to reduce future costs of the Medicare program. This could include required prescription drug discounts or rebates, which could limit net prices for our products. In addition, the health care reform legislation included language authorizing significant increases in Medicaid rebates that were effective in 2010, a new excise tax on prescription drugs financed by government programs, and new required discounts in the Medicare Part D program, all effective in 2011. There is a risk that government officials will continue to search for ways to reduce or control prices.

Europe. In Europe, our operations are subject to significant price and marketing regulations. Many governments are introducing healthcare reforms in a further attempt to curb increasing healthcare costs. In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general in the EU, particularly with regard to prescription drugs, has become very intense. Increasingly high barriers are being erected against the entry of new products, and payors are limiting access to innovative medicines based on cost-benefit analyses. In addition, prices for marketed products are referenced within Member States and across Member State borders, including new EU Member States. There is also a risk that certain Member States which currently use the euro as their currency, could cease to do so and issue their own de-valued currency. If this occurs then it could impact the effective prices we would be able to charge for our products. If the exiting Member State also serves as a reference country for other countries, then this devaluation could further substantially impact the effective prices we would be able to charge in such other countries.

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Japan. In Japan, the government generally introduces price cut rounds every other year, and the government additionally mandates price decreases for specific products. In 2012, the National Health Insurance price calculation method for new products and the price revision rule for existing products were reviewed, and the resulting new drug tariffs were effective beginning April 2012. The Japanese government is currently undertaking a healthcare reform initiative with a goal of sustaining the universal coverage of the National Health Insurance program, and is addressing the efficient use of drugs including promotion of generic use. Meanwhile, the government tentatively initiated a premium system which basically maintains the price of patented drugs for unmet medical needs in order to promote innovative new drug creation and the solution of the unapproved indication issue. The continuance of this system will be reviewed as a part of price reforms in 2014.

*Rest of World.* Many other countries around the world are also taking steps to rein in prescription drug prices. As an example, in 2012, China, one of our most important emerging growth markets, cut retail ceiling prices on 95 cancer, hematology and immunology drugs, including our *Femara*. The price cuts averaged approximately 17%, and more cuts are expected next year.

Regulations favoring generics. In response to rising healthcare costs, many governments and private medical care providers, such as Health Maintenance Organizations, have instituted reimbursement schemes that favor the substitution of generic pharmaceuticals for more expensive brand-name pharmaceuticals. In the US, generic substitution statutes have been enacted by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug instead of an original patented drug. Other countries have similar laws. We expect that the pressure for generic substitution will continue to increase.

Cross-Border Sales. Price controls in one country can also have an impact in other countries as a result of cross-border sales. In the EU, products which we have sold to customers in countries with stringent price controls can in some instances legally be re-sold to customers in other EU countries with less stringent price controls at a lower price than the price at which the product is otherwise available in the importing country. In North America, products which we have sold to customers in Canada, which has relatively stringent price controls, are sometimes re-sold into the US, again at a lower price than the price at which the product is otherwise sold in the US. Such imports from Canada and other countries into the US are currently illegal. However, political efforts continue at the US federal, state and local levels to change the legal status of such imports.

We expect that pressures on pricing will continue worldwide, and may increase. Because of these pressures, there can be no certainty that in every instance we will be able to charge prices for a product that, in a particular country or in the aggregate, enable us to earn an adequate return on our investment in that product.

### **Intellectual Property**

We attach great importance to patents, trademarks, copyrights and know-how, including research data, in order to protect our investment in research and development, manufacturing and marketing. It is our policy to seek the broadest protection available under applicable laws for significant product developments in all major markets. Among other things, patents may cover the products themselves, including the product's active ingredient and its formulation. Patents may cover processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen. In addition, patents may cover assays or tests for certain diseases or biomarkers, which will improve patient outcomes when administered certain drugs, as well as assays, research tools and other techniques used to identify new drugs. The protection offered by such patents extends for varying periods depending on the grant and duration of patents in the various countries or

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region. The protection afforded, which may vary from country to country, depends upon the type of patent and its scope of coverage.

In addition to patent protection, various countries offer data or marketing exclusivities for a proscribed period of time. Data exclusivity may be available which would preclude a potential competitor from filing a regulatory application for a set period of time that relies on the sponsor's clinical trial data, or the regulatory authority from approving the application. The data exclusivity period can vary depending upon the type of data included in the sponsor's application. When it is available, market exclusivity, unlike data exclusivity, precludes a competitor from obtaining FDA approval for a product even if a competitor's application relies on its own data.

### **United States**

Patents. In the US, a patent issued for an application filed today will receive a term of 20 years from the application filing date, subject to potential adjustments for Patent Office delay. A US pharmaceutical patent which claims a product, method of treatment using a product, or method of manufacturing a product, may be eligible for an extension of the patent term based on the time the FDA took to approve the product. This type of extension may only extend the patent term for a maximum of 5 years, and may not extend the patent term beyond 14 years from regulatory approval. Only one patent may be extended for any product based on FDA delay.

In practice, however, it is not uncommon for significantly more than the 5 year maximum patent extension period to pass between the time that a patent application is filed for a product and the time that the product is approved by the FDA. As a result, it is rarely the case that, at the time a product is approved by FDA, it will have the full 20 years of remaining patent life. Rather, in our experience, it is not uncommon that, at the date of approval, a product will have from 13 to 16 years of patent life remaining, including all extensions available at that time.

Data and Market Exclusivity. In addition to patent exclusivities, the FDA may provide data or market exclusivity for a new chemical entity or an "orphan drug," each of which run in parallel to any patent protection. Data exclusivity prevents a potential generic competitor from relying on clinical trial data which were generated by the sponsor when establishing the safety and efficacy of its competing product. Market exclusivity prohibits any marketing of the same drug for the same indication.

A new small-molecule active pharmaceutical ingredient shall have 5 years of data exclusivity, during which time a competitor generally may not submit an application to the FDA based on a sponsor's clinical data.

Orphan drug exclusivity provides 7 years of market exclusivity for drugs designated by the FDA as "orphan drugs," meaning drugs that treat rare diseases, as designated by the FDA. During this period, a potential competitor may not market the same drug for the same indication even if the competitor's application does not rely on data from the sponsor.

A new biologic active pharmaceutical ingredient shall have 12 years of market exclusivity, during which time a competitor may not market the same drug for the same indication.

The FDA may also request that a sponsor conduct pediatric studies, and in exchange will grant an additional 6-month period of market exclusivity, if the FDA accepts the data, the sponsor makes a timely application for approval for pediatric treatment, and the sponsor has either a patent-based or regulatory-based exclusivity period for the product which can be extended.

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### European Community

Patents. Patent applications in Europe may be filed in the European Patent Office (EPO) or in a particular country in Europe. The EPO system permits a single application to be granted for the whole of the EU, plus other non-EU countries, such as Switzerland and Turkey. A patent granted by the EPO or a European country office will expire no later than 21 years from the earliest patent application on which the patent is based. Pharmaceutical patents can also be granted a further period of exclusivity under the Supplementary Protection Certificate (SPC) system. SPCs are designed to compensate the owner of the patent for the time it took to receive marketing authorization by the European Health Authorities. An SPC may be granted to provide, in combination with the patent, up to 15 years of exclusivity from the date of the first European marketing authorization. But the SPC cannot last longer than 5 years. The SPC duration can additionally be extended by a further 6 months if the product is the subject of an agreed pediatric investigation plan. The post-grant phase of patents, including the SPC system, is currently administered on a country-by-country basis under national laws which, while differing, are intended to, but do not always, have the same effect.

As in the US, in practice, however, it is not uncommon for the granting of an SPC to not fully compensate the owner of a patent for the time it took to receive marketing authorization by the European Health Authorities. Rather, since it can often take from 5 to 10 years to obtain a granted patent in Europe after the filing of the application, and since it can commonly take longer than this to obtain a marketing authorization for a pharmaceutical product in Europe, it is not uncommon that a pharmaceutical product, at the date of approval, will have a patent lifetime of 10 to 15 years, including all extensions available at that time.

Data and Market Exclusivity. In addition to patent exclusivity, the EU also provides a system of regulatory data exclusivity for authorized human medicines, which runs in parallel to any patent protection. The system for drugs being approved today is usually referred to as "8+2+1" because it provides: an initial period of 8 years of data exclusivity, during which a competitor cannot rely on the relevant data; a further period of 2 years of market exclusivity, during which the data can be used to support applications for marketing authorization, but the competitive product cannot be launched; and a possible 1 year extension of the market exclusivity period if, during the initial 8 year data exclusivity period, the sponsor registered a new therapeutic indication with "significant clinical benefit." This system applies both to national and centralized authorizations. Since this system has been in force only since late 2005, the first 8 year period of data exclusivity has not yet expired, and many medicines are instead covered by the previous system in which EU member states provided either 6 or 10 years of data exclusivity.

The EU also has an orphan drug system for medicines similar to the US system. If a medicine is designated as an orphan drug, then it benefits from 10 years of market exclusivity after it is authorized, during which time a similar medicine for the same indication will not receive marketing authorization.

Japan

In Japan, a patent can be issued for active pharmaceutical ingredients. Although methods of treatment, such as dosage and administration, are not patentable in Japan, pharmaceutical compositions for a specific dosage or administration method are patentable. Processes to make a pharmaceutical composition are also patentable. The patent term granted is generally 20 years from the filing date of the patent application on which the patent is based. It can be extended up to 5 years under the Japanese Patent Act to compensate for erosion against the patent term caused by the time needed to obtain marketing authorization from the MHLW. Typically, it takes approximately 7 to 8 years to obtain marketing authorization in Japan. A patent application on a pharmaceutical substance is usually filed shortly before or at the time when clinical testing begins. Regarding compound patents, it commonly takes approximately 4 to 5 years or more from the patent application filing date to the date that the patent is

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ultimately granted. As a result, it is not uncommon for the effective term of patent protection for an active pharmaceutical ingredient in Japan to be approximately 20 to 21 years, if duly extended.

The following is a summary of the patent expiration dates for certain key products of our Pharmaceuticals Division:

#### Oncology

Gleevec/Glivec. We have patent protection on imatinib, the active ingredient used in our leading product Gleevec/Glivec, until July 2015 in the US (including pediatric extension), until 2016 in the major EU countries and until September 2014 for the main indications in Japan with generics authorized for a minor indication expected from December 2013. Additional patents were granted in more than 40 countries including the US, Japan, France, Germany, UK, Italy and Spain, claiming innovative features of Gleevec/Glivec, including crystal form (expiry 2018), tablet formulation (expiry 2023) and process (expiry 2023). Patent protection on a new crystal form of imatinib has been challenged in the US, but no challenge has been made to the compound patent in the US. In Turkey, generic competition launched in 2012, despite extended litigation. In Canada and Russia, the compound patent will expire in April 2013. Litigation is ongoing in both countries.

Tasigna. Patent protection for the active ingredient in Tasigna will expire in 2023 in the US and other major markets.

Zometa and Reclast/Aclasta. Patent protection on zoledronic acid, the active ingredient in these products, expired in 2012 in a limited number of smaller markets, and will expire in 2013 in the US and in other major markets. Additional patents claiming certain innovative forms or uses of these products have been granted in some countries including the US, UK, and the EU. These include a pharmaceutical product patent (US, expiry 2028), dosing regimen patent (US, expiry 2024; UK and EU, expiry 2021), and infusion time patent (Zometa only, US, expiry 2025). In the US, we settled patent litigation brought against a generic manufacturer who challenged our patent on zoledronic acid. Under the settlement agreement, the generic manufacturer has dropped its challenge against the compound patent and will not launch zoledronic acid in the US until after the patent expires in March 2013. Patent litigations are ongoing in the US against other generic manufacturers who have challenged the pharmaceutical product patent, but no additional US generic challenges have been made to the compound patent. Patent litigations are also ongoing against generic manufacturers in other countries including Australia (where we have obtained a preliminary injunction), Canada, and some European countries.

*Femara*. Patent protection for the active ingredient in *Femara* expired in 2011 in the US and in major European markets, and expired in 2012 in Japan. Data exclusivity in Japan expires in 2014. Generic versions of *Femara* are available now in all major markets with the exception of Japan.

Sandostatin. Patent protection for the active ingredient of Sandostatin has expired. Generic versions of Sandostatin SC are available in the US and elsewhere. Patents protecting the Sandostatin LAR formulation, the long-acting version of Sandostatin which represents a majority of our Sandostatin sales, expire in 2014 and beyond in the US, but expired in July 2010 in key markets outside the US.

*Exjade*. Patent protection for the active ingredient in *Exjade* will expire in 2019 in the US and in 2021 in other markets. In the US, a generic company has challenged the compound patent.

*Afinitor/Votubia* and *Zortress/Certican*. Patent protection for everolimus, the active ingredient in these products, and licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents, is expected to expire in 2020 in the US and in 2018-2019 in Europe and other major countries.

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*Jakavi*. Basic compound patent protection (including SPC) for *Jakavi* expires in 2027 in the EU. US rights to *Jakavi* are held by Incyte Corporation.

Signifor. Signifor is subject to patent protection in the US and EU until 2026.

#### Primary Care

#### Primary Care

*Arcapta/Onbrez.* Patent protection for the active ingredient of *Onbrez* (*Arcapta* in the US) is expected to expire in 2025 in the US (including patent term extension), in 2024 in Europe, and in 2020 in various other markets.

Diovan/Co-Diovan/Diovan HCT. Patent protection on valsartan, the active ingredient used in our long-time best-selling products Diovan and Co-Diovan/Diovan HCT, expired in the major countries of the EU in 2011, and in September 2012 in the US. As a result, Diovan and Co-Diovan/Diovan HCT face generic competition in those countries. With respect to the US, generic versions of Diovan HCT have launched in 2012. Generic versions of Diovan monotherapy have not yet launched in the US but could potentially launch at any time. Patent protection will expire in Japan in 2013 for Diovan and 2016 for Co-Diovan (including patent term extensions). Patent litigations are ongoing against generic manufacturers in Europe and Asia.

Exforge/Exforge HCT. Exforge is a single-pill combination of amlodipine besylate and valsartan. Exforge HCT is the single pill combination that also includes hydrochlorothiazide. The valsartan patents expired in many countries in 2011 and 2012, and will expire in 2013 in Japan (see above), except that, in Japan, the valsartan patent was extended for the Exforge product only to 2015. The patent on amlodipine besylate has expired. The patent covering the Exforge product (the combination of amlodipine besylate and valsartan) will expire in 2019 and has been challenged in both the US and Europe. In the US, under a license agreement with a generics manufacturer, the product is expected to face generic competition prior to patent expiry. We have regulatory exclusivity for the data generated for Exforge in Europe until 2017 and in Japan until 2014. However, there is a risk that generic manufacturers may circumvent regulatory exclusivity and gain approval of a combination valsartan-amlodipine product in Europe before 2017. The patent covering the Exforge HCT product (the combination of amlodipine besylate, hydrochlorothiazide and valsartan) will expire in 2023 and has been challenged in the US. In the US, under a license agreement with a generics manufacturer, the product is expected to face generic competition after Exforge.

*Seebri*. There is no patent protection on glycopyrronium, the active ingredient in *Seebri*. A number of patents covering the formulations, commercial product and uses of this product expire by 2025. In addition, *Seebri* is entitled to regulatory exclusivity for the data generated for approval until 2022 in the EU, and until 2020 in Japan.

*Tekturna/Rasilez* and combination products. Patent protection for aliskiren, the active ingredient of *Tekturna/Rasilez*, and various single-pill combination products, will expire in 2018 in the US (not including pediatric extension) and between 2015 and 2020 in other markets.

*Galvus* and *Eucreas*. Patent protection for vildagliptin, the active ingredient of *Galvus*, and the patented active ingredient in *Eucreas*, is estimated to expire, with extensions, in 2019 to 2024.

Established Medicines

Voltaren/Cataflam. Patent protection for the active ingredient in Voltaren has expired worldwide.

*Ritalin LA/Focalin XR*. There is no patent protection for the active ingredient in *Ritalin* or *Focalin*. A number of patents covering the formulation will expire in 2015 and 2019. Several generic manufacturers have filed applications to market generic versions of *Ritalin LA* and *Focalin XR* in the US. Some of these patent litigations have been settled. Litigation against several generic manufacturers was initiated in the US. These patent litigations have been settled.

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Specialty Care

Ophthalmology

Lucentis. Patent protection for the active ingredient in Lucentis expires in 2018-22 in the EU and Japan. We do not have rights to market the product in the US. In December 2009, MedImmune filed a patent infringement suit against us in the UK and elsewhere in Europe, alleging that Lucentis infringes MedImmune's patents. MedImmune's European patents expired in 2011, but have been extended to 2016 in several European countries, including Italy, Germany, the UK, and France, and may be extended elsewhere in Europe. We have filed countersuits throughout Europe alleging non-infringement and invalidity. For more information regarding the Lucentis litigation see "Item 18. Financial Statements" note 20". These litigations have been settled.

### Neuroscience

Gilenya. Patent protection for fingolimod, the active ingredient in Gilenya (licensed from Mitsubishi Tanabe Pharma Corporation), is expected to expire in 2019 in the US (including a 5-year patent term extension) and in 2018 in Europe (including a 5-year patent term extension). In Europe, we have regulatory exclusivity for the data generated for approval of Gilenya until 2021, which could possibly be extended by one year. A patent for the commercial formulation of Gilenya has been granted in most major markets. This patent will expire in 2024 in most countries, including the EU and Japan, and in 2026 in the US. In addition, a patent application is pending in the US for the commercial formulation of Gilenya which, if granted, would expire in 2024.

Exelon. Patent protection for the active ingredient in Exelon, granted to Proterra and licensed to Novartis, expired in August 2012 in the US and in 2011 in most other major markets. We hold a patent on a specific isomeric form of the active ingredient used in Exelon which expires in 2014 in the US. Exelon Patch is further covered by a formulation patent expiring in 2019 in major markets. We settled litigation with several generic manufacturers who had filed applications to market generic versions of Exelon capsules in the US and had challenged our patents covering capsule formulations. Under the terms of the settlement agreements, Novartis granted these generic manufacturers licenses to the challenged US patents. As a result, generic versions of Exelon capsules are now on the market. The agreements do not permit the generic manufacturers to launch a generic version of the Exelon Patch prior to the patent expiration date. In April 2011, however, two generic manufacturers filed applications to market generic versions of the Exelon Patch in the US, and challenged the patents covering the Patch. We filed infringement lawsuits against both of these manufacturers. The remaining patent covering the oral form in Europe (the patent on the specific isomeric form) expired in July 2012; litigation relating to this patent continues in several European countries. In 2012 we became aware that generic rivastigmine patches were being developed and manufactured in South Korea for markets including the EU. We have filed an infringement lawsuit under our Korean patents.

*Extavia*. Patent protection for the active ingredient in *Extavia* has expired. In May 2010, Biogen Idec filed a patent infringement suit in the US against Novartis, alleging that *Extavia* infringes its patent. The recently-granted Biogen Idec patent will expire in September 2026. The litigation is ongoing.

Comtan. Patent protection for entacapone, the active ingredient in Comtan, which we licensed from Orion, expired in Europe in 2012, and will expire in the US in 2013. Other patents, such as a polymorph patent, have also been granted. US litigation concerning the patent on entacapone by Orion against two generic manufacturers who have challenged these patents has been settled. Under the terms of the settlement agreements, the first-to-file generic challenger launched a generic version of Comtan in September 2012, prior to the expiration of the US entacapone compound patent. The second generic challenger can launch a generic version of Comtan in the US in April 2013. Suit against a third generic manufacturer is ongoing in the US. Novartis was not a party to any of these litigations. In Europe, several generic manufacturers have obtained marketing authorizations.

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Stalevo. One of the active ingredients in Stalevo is entacapone, the active ingredient in Comtan. Patent protection for entacapone expired in 2012 in Europe, and will expire in the US in 2013 (see above). Stalevo is protected by additional patents expiring up to 2020. Patent litigation by Orion in the US against generic manufacturers who have challenged the patent on entacapone and Stalevo formulation patents has been settled. As a result, generic versions of Stalevo were launched in April 2012. Novartis was not a party to the litigation.

Integrated Hospital Care

*Ilaris.* Patent protection for the active ingredient in *Ilaris* is expected to expire in 2024 in the US and in 2024 in Europe.

Neoral/Sandimmune. Patent protection for the cyclosporin ingredient of Neoral/Sandimmune has expired worldwide.

*Myfortic*. There is no patent protection for the active ingredient in *Myfortic*. Patents covering the formulation will expire in 2017. Several generic manufacturers have filed applications to market generic versions of *Myfortic* in the US. Three patent litigations have been settled. In Europe, generic manufacturers are seeking approval for generic versions *Myfortic* in some European countries.

#### Critical Care

*Xolair.* Patent protection for the active ingredient in *Xolair* will expire in 2018 in the US, in 2017 in Europe and in Japan (if the patent term extension pending there is granted), and expired in 2012 in Canada and Hong Kong. No biosimilar competitors have launched to date.

*TOBI Podhaler.* There is no patent protection for the active ingredient tobramycin. Patents covering the commercial product will expire from 2018 to 2022 in the US and EU. Additional patent applications are also pending with respect to the commercial product in the US and the EU. If the last-filed of these applications were granted, then that patent would expire in 2025. In addition, in Europe, the product is entitled to Orphan Drug Status until 2021 for the current approved indication.

### Compounds in Development

We file patent applications on our Compounds in Development during the course of the development process. The length of the term of any patents on our Compounds in Development cannot be known with certainty until after a compound is approved for marketing by a health authority. This is so because patent applications for many of the compounds will be pending during the course of the development process, but not yet granted. In addition, while certain patents may be applied for early in the development process, such as for the compound itself, it is not uncommon for additional patent applications to be applied for throughout the development process, such as for formulations, or additional uses. Further, in certain countries, data exclusivity and other regulatory exclusivity periods may be available, and may impact the period during which we would have the exclusive right to sell a product. These exclusivity periods generally run from the date the products are approved, and so their expiration dates cannot be known with certainty until the product approval dates are known. Finally, in the US and other countries, pharmaceutical products are eligible for a patent term extension for patent periods lost during product development and regulatory review. The law recognizes that product development and review by the FDA and other health authorities can take an extended period, and permits an extension of the patent term for a period related to the time taken for the conduct of clinical trials and for the health authority's review. However, the length of this extension and the patents to which it applies cannot be known in advance, but can only be determined after the product is approved.

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Subject to these uncertainties, we provide the following information regarding our Compounds in Phase III Clinical Development, if any, which have been submitted for registration to the FDA or the EU's EMA:

QVA149. QVA149 is product which combines indacaterol, the active ingredient in *Arcapta/Onbrez*, with glycopyrronium, the active ingredient in *Seebri*. Patent protection for indacaterol is expected to expire in 2025 in the US (including patent term extension), in 2024 in Europe (including extensions(,, and in 2020 in various other markets. There is no compound patent protection on glycopyrronium, but there are patents and patent applications for the dry powder formulation technology that apply to both *Seebri* and QVA149. In addition, there are patents and patent applications for the combination of indacaterol and glycopyrronium that are due to expire in 2025.

RLX030. Patent protection for the serelaxin molecule (human relaxin-2) has expired and the patents covering the formulation and process will expire shortly after the product's projected launch date. A patent covering the method of using serelaxin to treat acute heart failure has been granted in the US and expires in 2029. This use patent is now under examination worldwide in markets that permit use patents. Serelaxin is entitled to post-approval regulatory exclusivity for 12 years in the US, 11 years in Europe and 8 years in Japan.

The loss of patent protection can have a significant adverse impact on our Pharmaceuticals Division. There is also a risk that some countries, particularly countries in the developing world, may seek to impose limitations on the availability of patent protection for pharmaceutical products, or on the extent to which such protections may be enforced. In addition, even though we may own or license patents protecting our products, and conduct pre-launch freedom-to-operate analyses, a third party may nevertheless claim that one of our products infringes an unlicensed third-party patent. In addition, despite data exclusivity, a competitor could opt to incur the costs of conducting its own clinical trials and preparing its own regulatory application, and avoid data exclusivity altogether. As a result, there can be no assurance that our efforts to protect our intellectual property will be effective, or that we will be able to avoid substantial adverse effects from the loss of patent protection in the future.

#### ALCON

Our Alcon Division is a leader in the research, development, manufacturing and marketing of eye care products worldwide. As of December 31, 2012, the Alcon Division employed 23,874 full-time equivalent associates worldwide in 75 countries. In 2012, the Alcon Division had consolidated net sales of \$10.2 billion representing 18.0% of total Group net sales.

Alcon is a global leader in eye care and with the April 2011 completion of the merger of Alcon into Novartis, eye care became our fifth growth platform alongside innovative pharmaceuticals, generics, vaccines and diagnostics, and consumer health. The 2011 merger united the strengths of Alcon, CIBA Vision and Novartis Ophthalmics into one eye care business. See "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Acquisitions, Divestments and Other Significant Transactions Acquisitions in 2011 Corporate Alcon, Inc." Our Alcon Division offers an extensive breadth of products serving the full lifecycle of patient needs across eye diseases, vision conditions and refractive errors, and is our second largest Division based on sales.

To meet the needs of ophthalmologists, surgeons, optometrists, opticians and physician specialists, Alcon operates with three businesses: Surgical, Ophthalmic Pharmaceuticals and Vision Care. Alcon sells products in 180 markets, and runs operations in 75 countries. Each business operates with specialized sales forces and marketing support.

Alcon's dedication to research and development is important to our growth plans. As part of our efforts, the Alcon Division works together with the Novartis Institutes for BioMedical Research (NIBR), our global pharmaceutical research organization. This collaboration allows our Alcon Division to leverage

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the resources of NIBR in an effort to discover and expand ophthalmic research targets and to develop chemical and biologic compounds for the potential development in diseases of the eye, with a particular focus on diseases such as glaucoma and macular degeneration.

In March 2012, Alcon gained exclusive rights from ThromboGenics to commercialize ocriplasmin outside the US. Ocriplasmin is potentially the first pharmacological treatment for vitreomacular traction and macular hole in Europe. Ocriplasmin has been submitted for approval in the EU under the brand name *Jetrea*, and in January 2013 received a positive CHMP opinion. In October 2012, ocriplasmin was approved by the FDA.

In the summer of 2012, Alcon acquired Endure Medical Systems. The acquisition enables Alcon to enter into the ophthalmic microscopy field through the addition of the *LuxOR* Microscope, which has applications for both cataract, as well vitreoretinal surgeries. Products are expected to be introduced globally in 2013.

To further improve patient outcomes in cataract surgery, Alcon acquired the ophthalmic division of SensoMotoric Instruments in November 2012, providing Alcon with leading ocular surgical guidance technology. Alcon also agreed to acquire, from Jack Holladay, MD, and software developer Athanassios Kontos, the rights to certain surgical guidance and planning software used in cataract procedures.

In April 2011, Alcon's portfolio of generic ophthalmic medicines sold through its Falcon business unit primarily in the US, was integrated into our Sandoz Division. Alcon will continue to manufacture the Falcon generics products and supply them to Sandoz. See "Sandoz."

#### **Alcon Division Products**

Surgical

Our Alcon Division's Surgical business is the market leader in global ophthalmic surgical product revenues, according to Market Scope, offering ophthalmic surgical equipment, instruments, disposable products and intraocular lenses for surgical procedures that address cataracts, vitreoretinal conditions, glaucoma and refractive errors.

Alcon's Surgical portfolio includes the *Infiniti* vision system to perform cataract surgeries, the *Constellation* vision system for retinal operations, and the *Wavelight* refractive suite for refractive procedures. Alcon also offers the *AcrySof* family of intraocular lenses (IOLs) to treat cataracts, including the *AcrySof* IQ, *AcrySof* IQ *ReSTOR*, *AcrySof* IQ *Toric* and *AcrySof* IQ *ReSTOR Toric* IOLs, as well as the *LenSx* femtosecond laser, a cataract surgery technology that increases precision and reproducibility for the corneal incision, capsulorhexis and lens fragmentation steps of the procedure. In addition, Alcon provides advanced viscoelastics, surgical solutions, surgical packs and other disposable products for cataract and vitreoretinal surgery.

#### Ophthalmic Pharmaceuticals

Our Alcon Division's Ophthalmic Pharmaceuticals business combines Alcon's broad range of pharmaceuticals with selected ophthalmic products (excluding *Lucentis*) previously marketed by the Novartis Pharmaceuticals Division. The products treat chronic and acute conditions of the eye including glaucoma, elevated intraocular pressure (associated with glaucoma), eye infection and inflammation, eye allergies, and dry eye. Our Alcon Division's Ophthalmic Pharmaceuticals business also oversees the line of professionally driven over-the-counter brands that include artificial tears and ocular vitamins. Product highlights within our Alcon Division's Ophthalmic Pharmaceuticals portfolio include *Travatan Z* ophthalmic solution and *DuoTrav* ophthalmic solution for the treatment of elevated intraocular pressure associated with glaucoma; *Vigamox* ophthalmic solution for bacterial conjunctivitis; *Pataday* ophthalmic solution for ocular itching associated with allergic conjunctivitis; *Nevanac* ophthalmic suspension for eye inflammation following cataract surgery, and the *Systane* family of over-the-counter products for dry eye relief.

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Vision Care

Our Alcon Division's Vision Care business combines the portfolio of contact lenses and lens care products formerly sold by our former CIBA Vision Business Unit, with Alcon's contact lens care solution portfolio. This includes the *Opti-Free* line of multi-purpose disinfecting solutions, as well as the *Clear Care* and *AOSept Plus* hydrogen peroxide lens care solutions. Alcon also offers a broad portfolio of silicone hydrogel, daily disposables and color contact lenses, including our *Air Optix*, *Dailies* and *Freshlook* brands, as well as our latest innovation of *Dailies Total1*. Through the integration of CIBA Vision products, Alcon is now one of the largest manufacturers across contact lenses and lens care products.

#### **New Products**

Alcon launched a number of significant products in 2012, and also received a number of key approvals, including:

*Dailies Total1* lenses Water gradient daily disposable contact lenses received US and Japan approval in 2012. Also in 2012, *Dailies Total1* contact lenses launched in Germany, Austria, Italy and France.

*Opti-Free PureMoist* Multi Purpose Disinfecting Solution launched throughout 2012 in a number of Asian countries (including Japan and Singapore), Europe (including Russia and Italy), and South America.

Air Optix Night and Day Aqua silicone hydrogel contact lenses launched throughout 2012 in South Africa and Australia, as well as in select countries in Europe, Latin and South America, and Asia.

Dailies Illuminate color contact lenses introduced the new color, Rich Brown, in Japan, Hong Kong, Malaysia and Korea.

AcrySof IQ ReSTOR +2.5D Multifocal IOL and AcrySof IQ ReSTOR +2.5D Multifocal Toric IOL advanced technology intra-ocular lenses launched in countries that recognize the CE Mark in September 2012 as a line extension of the already marketed AcrySof IQ ReSTOR +3.0D Multifocal IOL and AcrySof IQ ReSTOR+3.0D Multifocal Toric IOL. advanced technology IOL lenses correct cataracts, as well as refractive errors like presbyopia and astigmatism,,offering improved near and intermediate vision.

*LenSx* femtosecond cataract refractive laser received additional indication by the FDA, and can now be used for corneal flap creation during refractive surgical procedures.

LenSx SoftFit Patient Interface Alcon's latest innovation introduced within the LenSx laser platform launched in the US for use during cataract surgery, enabling easier docking, free floating capsulotomies, lower intra-ocular pressure and improved surgical performance.

Centurion Alcon's next generation phacoemulsification system received FDA approval to perform cataract surgeries.

LuxOR Ophthalmic Microscope re-launched in the US in July 2012. This addition broadens Alcon's surgical portfolio by expanding into the optical microscope segment of the market, and offering a solution for improved intra-operative visualization.

*Durezol* FDA approval received for the indication of uveitis. The product was originally indicated for use as an anti-inflammatory for the eye post-surgery. The new indication for uveitis will treat inflammation in the uvea near the middle of the eye.

*Nevanac* EMA approval received for the indication of prevention of post-surgical macular edema*Nevanac* was originally indicated to treat pain and inflammation associated with cataract surgery.

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The new indication for prevention of post-surgical macular edema will treat the inflammatory response in the retina that limits achieving quality vision post cataract surgery.

 $\it Ilevro$  (nepafenac ophthalmic suspension), 0.3% FDA approval received for the treatment of pain and inflammation associated with cataract surgery.

### Key Marketed Alcon Products

The following tables set forth certain key marketed products in our Alcon Division. While we intend to sell our marketed products throughout the world, not all products and indications are currently available in every country.

Surgical

Cataract Infiniti vision system with the OZil torsional hand piece for cataract procedures

Acrysof family of intraocular lenses includes but is not limited to: Acrysof IQ ReSTOR, Acrysof IQ Toric and Acrysof IQ ReSTOR Toric advanced technology intraocular lenses that correct cataracts

with presbyopia and/or astigmatism.

LenSx Laser used for specific steps in the cataract surgical procedure

LuxOR Microscope used for ophthalmic surgical procedures

Vitroretinal Constellation vision system for vitreoretinal operations

Constellation Ultravit vitrectomy probe

Vitrectomy Probes in 23G, 25+ Purepoint Laser System

Grieshaber surgical instruments

Edgeplus Blade Trocar Cannula System

Refractive Allegretto Wave Eye-Q Excimer Laser for LASIK vision correction

Wavelight FS200 laser for specific steps in LASIK surgical procedures

Wavelight EX500 laser for LASIK vision correction

Acrysof Cachet phakic intraocular lens that corrects moderate to high myopia

Glaucoma EX-PRESS Glaucoma Filtration Device

In addition, Alcon provides advanced viscoelastics, surgical solutions, surgical packs and other disposable products for cataract and vitreoretinal surgery.

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Ear Infections

Ophthalmic Pharmaceuticals

Glaucoma Travatan and Travatan Z Ophthalmic Solutions to lower intraocular pressure

Azopt Ophthalmic Suspension to lower intraocular pressure Duotrav Ophthalmic Solution to lower intraocular pressure

(outside US markets)

Azarga Ophthalmic Suspension to lower intraocular pressure

(outside US markets)

Nyogel reduction of intraocular pressure

Anti-Infectives Vigamox and Moxeza Ophthalmic Solution for treatment of bacterial conjunctivitis

Okacin ophthalmic solution for treatment of bacterial conjunctivitis

(Turkey only)

Anti-Inflammation Nevanac Ophthalmic Suspension to treat pain following cataract surgery

Durezol Emulsion to treat pain and inflammation associated with eye surgery

TobraDex and TobraDex ST Ophthalmic Suspensions, combination anti-infective/anti-inflammatory

products

Voltaren Ophtha Treatment of postoperative inflammation after cataract surgery, temporary relief of

pain and photophobia after refractive surgery

Dry Eye The Systane family of over-the-counter dry eye products:

Systane Balance Lubricant Eye Drops Systane Ultra Lubricant Eye Drops Systane Lubricant Eye Drops

Systane Gel Drops Systane Lid Wipes

Lubricants for eye dryness, discomfort or ocular fatigue:

Genteal Viscotears

Oculotect (outside US markets)

Hypotears

Allergy Patanol and Pataday Ophthalmic Solutions for ocular itching associated with allergic conjunctivitis

Patanase nasal spray for seasonal nasal allergy symptoms

Zaditor Antihistamine Eye Drops for temporary relief of itchy eyes associated with eye allergies

(over-the-counter in the US)

Zaditen Ophtha an H1-antagonist to fight allergic conjunctivitis

*Livostin* an H1-antagonist to fight allergic conjunctivitis (Canada only) *Ciprodex*\* Otic Suspension to treat middle and outer ear infections

Ocular Nutrition ICaps eye vitamin dietary supplements provide essential dietary ingredients to support eye health

Vitalux nutrient supplements help patients with age-related macular degeneration maintain their vision

(outside US markets)

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Other Products Antikatarata supplementary treatment of lens opacities (Russia only)

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CiproDex® is a registered trademark of Bayer, AG.

Vision Care

Contact Lenses Air Optix family of silicone hydrogel contact lenses

Dailies family of daily disposable contact lenses

FreshLook family of color contact lenses

Dailies Total1 water gradient silicone hydrogel contact lenses

Contact Lens Care Opti-Free PureMoist MPDS

Opti-Free RepleniSH MPDS Opti-Free Express MPDS

Clear Care Cleaning and Disinfecting Solution (AOSept Plus outside of North America)

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## Alcon Products in Development

			Planned	
Franchise Surgical	Project/Compound  AcrySof IQ ReSTOR IOL (new design)	Condition Cataract	filing dates US 2013 EU 2012 Jpn 2013	Current phase Advanced development Approved Advanced development
	AcrySof IQ ReSTOR Toric IOL (new design)	Cataract	US 2014 EU 2012 Jpn 2015	Advanced development Approved Advanced development
	Next generation Phaco system	Cataract	US 2012 EU 2013 Jpn 2013	Approved Advanced development Advanced development
	AcrySof IQ ReSTOR Toric IOL	Cataract	US 2014 Jpn 2014	Advanced development Advanced development
	AcrySof IQ ReSTOR Toric IOL diopter range expansion	Cataract	US 2013 Jpn 2013	Advanced development Advanced development
	AcrySof IQ Toric IOL low diopter range expansion	Cataract	US 2013 Jpn 2013	Advanced development Advanced development
	AcrySof Cachet angle-supported phakic lens	Refractive	US 2013 <sup>(1)</sup> Jpn 2013	Advanced development Advanced development
	Next generation IOL	Cataract	US 2013 EU 2013 Jpn 2014	Advanced development Advanced development Advanced development
	Infiniti system upgrade	Cataract	US Filed Jpn 2012	Approved Filed
	Allegretto EX-500 laser, new indication	Refractive	US 2015	Advanced development
	LenSx Laser, system expansion	Cataract	US 2013 EU 2013 Jpn 2015	Advanced development
	LuxOr microscope	Cataract	EU 2013	Advanced development

US 2013 EU 2013 Jpn 2014 Luxite microscope Cataract Advanced development

This application was withdrawn in 2011 per FDA recommendation and will be re-filed in 2013 with complete 5-year data.

(1)

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Franchise Ophthalmic Pharmaceuticals	<b>Project/Compound</b> Azorga solution	<b>Condition</b> Glaucoma	Planned filing dates Jpn 2012	<b>Current phase</b> Filed
	Brinzolamide/Brimonidine fixed combination	Glaucoma	US 2012 EU 2013	Filed Phase III
	Travoprost, new formulation	Glaucoma	US 2013 EU 2012	Phase III Filed
	Nepafenac, new formulation	Anti-inflammatory	US 2011 EU 2012	Approved Filed
	Olopatadine, new formulation	Ocular allergy	US 2013	Phase III
	AL-60371	Otic infections	US 2013	Phase III
	Jetrea (ocriplasmin)	Retina	EU 2011	Filed
Vision Care	New Toric Lens Design	Contact lens	US 2012 EU 2012 Jpn 2012	Filed Approved Filed
	New Multi-focal Design	Contact lens	US 2013 EU 2013 Jpn 2013	Advanced development
	New Color Lens Design	Contact lens	US 2013 EU 2013 Jpn 2014	Advanced development
	New Lens Solution	Lens Solution	US 2014 EU 2014	Advanced development

## **Principal Markets**

The principal markets for our Alcon Division include the US, Americas (except the US), Japan and Europe. The following table sets forth the aggregate 2012 net sales of the Alcon Division by region:

Alcon Division	2012 Net Sales to third parties	
	\$ millions	%
United States	4,016	39.3
Americas (except the United States)	1,104	10.8
Europe	2,710	26.5
Rest of the World	2,395	23.4
Total	10,225	100.0
	\$ millions	%
Established Markets*	7,805	76.3
Emerging Growth Markets*	2,420	23.7
Total	10,225	100.0

"Established Markets" are US, Canada, Western Europe, Australia, New Zealand and Japan. "Emerging Growth Markets" are all other markets.

Sales of certain eye care ophthalmic pharmaceutical products, including those for allergies, anti-inflammatory and dry eye, are subject to seasonal variation. Sales of the majority of our other products are not subject to material changes in seasonal demand.

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### **Research and Development**

In 2012, the Alcon Division expensed \$975 million (on a core basis \$950 million) in research and development, which amounted to 9.5% of the Division's net sales. The Alcon Division expensed \$892 million (on a core basis \$869 million) and \$352 million (on a core basis \$351 million) in research and development in 2011 and 2010, respectively.

The Alcon Division has more than 2,100 associates dedicated to research and development, working to address diseases and conditions that affect vision, such as cataracts, glaucoma, retina diseases, dry eye, infection, ocular allergies and refractive error. Our Alcon Division plans to invest more than \$5 billion over the next five years to drive research and new product development in eye care. Alcon's pipeline strategy is built around a proof-of-concept qualification process, which quickly identifies opportunities that have the best chance for technical success and advances those projects, while terminating others with a low probability of success.

The Novartis Institutes for BioMedical Research (NIBR) is the Novartis global pharmaceutical research organization that works to discover innovative medicines that treat disease and improve human health. See "Pharmaceuticals Research and Development." For Alcon's pharmaceutical business, NIBR engages in research activities in an effort to discover and expand ophthalmic research targets, and to develop chemical and biologic compounds for the potential development in diseases of the eye, with a particular focus on diseases such as glaucoma and macular degeneration. The costs for these activities are allocated to Alcon.

Research and development activities for Alcon's surgical business are focused on expanding intraocular lens capabilities to improve refractive outcomes and developing instruments for cataract, vitreoretinal and corneal refractive surgeries. The focus for the Vision Care business is on the research and development of new lens materials, coatings and designs to improve patient comfort, and on lens care solutions that provide the safety, disinfecting and cleaning power needed to help maintain ocular health.

### **Production**

We manufacture our Alcon Division's pharmaceutical products at eight facilities in the United States, Belgium, France, Spain, Brazil, Mexico and Singapore. Our Alcon Division's surgical equipment and other surgical medical devices are manufactured at ten facilities in the United States, Belgium, Switzerland, Ireland, Germany and Israel. Our Alcon Division's contact lens and certain lens care production facilities are in the US, Canada, Germany, Singapore, Malaysia and Indonesia.

The goal of our supply chain strategy is to efficiently produce and distribute high quality products. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may also rely on a single source of supply.

The manufacture of our products is complex and heavily regulated, which means that supply is never guaranteed. Like our competitors, our Alcon Division has faced manufacturing issues, and has received Warning Letters relating to such manufacturing issues. In particular, in December 2012, Alcon received an FDA Warning Letter following an inspection at the *LenSx* laser manufacturing site in Aliso Viejo, California. Alcon has responded in writing to the FDA and is committed to addressing these observations and collaborating with the Agency to ensure that they are fully resolved. The items noted in the Warning Letter do not affect the safety or effectiveness of the *LenSx* laser, or impact Alcon's ability to sell the product.

If we or our third-party suppliers fail to comply fully with regulations then there could be a product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of such events or other unforeseen

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catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

### **Marketing and Sales**

Our Alcon Division conducts sales and marketing activities around the world in 75 countries organized under five operating regions (US and Canada, Europe/Middle East/Africa, Latin America/Caribbean, Asia and Japan). The global sales force is organized around the Surgical, Ophthalmic Pharmaceuticals and Vision Care businesses.

Most of our global Alcon marketing efforts are supported by advertising in trade publications and by marketing and sales representatives attending regional and national medical conferences. Marketing efforts are reinforced by targeted and timely promotional materials and direct mail to eye care practitioners in the office, hospital or surgery center setting. Technical service after the sale is provided and an integrated customer relationship management system is in place in many markets. Where applicable in our Pharmaceutical and Vision Care business, direct-to-consumer marketing campaigns are executed to promote selected products.

While our Alcon Division markets all of its products by calling on medical professionals, direct customers and distribution methods differ across business lines. Although physicians write prescriptions, distributors, wholesalers, hospitals, government agencies and large retailers are the main direct customers for Alcon ophthalmic pharmaceutical products. Alcon surgical products are sold directly to hospitals and ambulatory surgical centers, although Alcon sells through distributors in certain markets outside the US. In most countries, contact lenses are available only by prescription. Our contact lenses can be purchased from eye care professionals, optical chains and large retailers, subject to country regulation. Lens care products can be found in major drugstores, food, mass merchandising and optical retail chains globally, subject to country regulations. In addition, mail order and Internet sales of contact lenses are becoming increasingly important channels in major markets worldwide.

As a result of the changes in healthcare economics, managed care organizations have become the largest group of payors for healthcare services in the US. In an effort to control prescription drug costs, almost all managed care organizations use a formulary that lists specific drugs that can be prescribed and/or the amount of reimbursement for each drug. We have a dedicated managed care sales team that actively seeks to optimize formulary positions for our products.

### Competition

The eye care industry is highly competitive and subject to rapid technological change and evolving industry requirements and standards. Companies within this industry compete on technological leadership and innovation, quality and efficacy of their products, relationships with eye care professionals and healthcare providers, breadth and depth of product offering and pricing. The presence of these factors varies across our Alcon Division's product offerings, which provides a broad line of proprietary eye care products and competes in all major product categories in the eye care market, with the exception of eyeglasses.

Even if our principal competitors generally do not have a comparable range of products, they can, and often do, form strategic alliances and enter into co-marketing agreements to achieve comparable coverage of the ophthalmic market. Particularly in the US, our branded OTC products compete against "store brand" products that are made with similar active ingredients as Alcon's. These products do not carry our Alcon Division's trusted brand names, but they also do not carry the burden of the expensive advertising and marketing which helped to establish a demand for the product. As a result, the store brands may be sold at lower prices. In recent years, consumers have increasingly begun to purchase store brand OTC products instead of branded products.

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#### Regulation

Our Ophthalmic Pharmaceuticals products are subject to the same regulatory procedures as are the products of our Pharmaceuticals Division. See " Pharmaceuticals Regulation."

Our Surgical and Vision Care products are regulated as medical devices in the US and the EU. These jurisdictions each have risk-based classification systems that determine the type of information which must be provided to the local regulators in order to obtain the right to market a product. In the US, safety and effectiveness information for Class II and III devices must be reviewed by the FDA. There are two review procedures: a Pre-Market Approval (PMA) and a Pre-Market Notification (510(k)) submission. Under a PMA, the manufacturer must submit to the FDA supporting evidence sufficient to prove the safety and effectiveness of the device. The FDA review of a PMA usually takes 180 days from the date of filing of the application. Under Pre-Market Notification (510(k)), the manufacturer submits notification to the FDA that it intends to commence marketing the product, with data that establishes the product as substantially equivalent to another product already on the market. The FDA usually determines whether the device is substantially equivalent within 90 days.

In the EU, the CE marking is required for all medical devices sold. By affixing the CE marking, the manufacturer certifies that a product is in compliance with provisions of the EU's Medical Device Directive. Most such products are subject to a self-certification process by the manufacturer, which requires the manufacturer to confirm that the product performs to appropriate standards. This allows the manufacturer to issue a Declaration of Conformity and to notify competent authorities in the EU that the manufacturer intends to market the product. In order to comply with European regulations, our Alcon Division maintains a full Quality Assurance system and is subject to routine auditing by a certified third party (a "notified body") to ensure that this quality system is in compliance with the requirements of the EU's Medical Device Directive as well as the requirements of the ISO quality systems' standard ISO 13485.

### **Intellectual Property**

We attach great importance to patents, trademarks, copyrights and know-how in order to protect our investment in research and development, manufacturing and marketing. It is our policy to seek the broadest possible protection for significant product developments in all major markets. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen.

The protection offered by such patents extends for varying periods depending on the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage. We monitor our competitors and vigorously challenge infringements of our intellectual property.

Worldwide, all of our major products are sold under trademarks that we consider in the aggregate to be important to our businesses as a whole. We consider trademark protection to be particularly important in the protection of our investment in the sales and marketing of our Surgical, Pharmaceutical and Vision Care businesses. The scope and duration of trademark protection varies widely throughout the world. In some countries, trademark protection continues only as long as the mark is used. Other countries require registration of trademarks and the payment of registration fees. Trademark registrations are generally for fixed, but renewable, terms.

We rely on copyright protection in various jurisdictions to protect the exclusivity of the code for the software used in our surgical equipment. The scope of copyright protection for computer software varies throughout the world, although it is generally for a fixed term which begins on the date of copyright registration.

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### **SANDOZ**

Our Sandoz Division is a leader in developing, manufacturing and marketing generic pharmaceutical products, follow-on biopharmaceutical products and drug substances that are not protected by valid and enforceable third-party patents. As of December 31, 2012, affiliates of the Sandoz Division employed 25,835 full-time equivalent associates worldwide, and sells products in approximately 140 countries. In 2012, the Sandoz Division achieved consolidated net sales of \$8.7 billion, representing 15.4% of the Group's total net sales.

The Sandoz Division develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical and biotechnological active substances, which are not protected by valid and enforceable third-party patents. Sandoz has activities in Retail Generics, Anti-Infectives, Biopharmaceuticals, Oncology Injectables, Ophthalmis, Respiratory and Dermatology. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and sells biotechnology manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market. Sandoz Ophthalmics, which was formed through the integration of Alcon's generic division Falcon, develops, manufactures and markets generic ophthalmic and otic products. In addition, Sandoz expanded its presence in Respiratory through the acquisition of Oriel Therapeutics in 2010, and expanded its presence in Dermatology through the acquisition of specialty dermatology company Fougera Pharmaceuticals in 2012.

Sandoz has three strategic priorities: to be first-to-market as originators' substance patents expire or become unenforceable, to be cost competitive by leveraging economies of scale in production and development, and to differentiate Sandoz based on its extensive global reach and advanced technical expertise in the development, manufacturing and marketing of differentiated generics and biosimilars.

According to IMS Health, Sandoz is the second-largest company in worldwide generic sales and is the global leader in biosimilars, with three marketed medicines accounting for approximately half of all biosimilars in the combined regions of North America, Europe, Japan and Australia. In addition, we have a pipeline of eight to ten biosimilar molecules including biosimilar rituximab (sold by Roche under the brand names Rituxan®/Mabthera®) and other monoclonal antibodies at various stages of development. Our 2010 launch of generic enoxaparin sodium (sold by Sanofi under the brand name Lovenox®) in the US, for which we recorded more than \$1 billion net sales in its first 12 months on the market, also helped Sandoz to achieve a global leadership position in generic injectables, based on IMS Health figures. With the integration of Falcon Pharmaceuticals, Sandoz is now positioned as a leading seller of generic ophthalmic medicines. In addition, Sandoz remains one of the leading manufacturers of antibiotics worldwide.

In July 2012, Sandoz completed the acquisition of Fougera Pharmaceuticals for \$1.525 billion in an all-cash transaction. This acquisition makes Sandoz a leader in generic dermatology medicines globally, and further strengthens Sandoz's differentiated products strategy. Fougera is a specialty dermatology business which had 2011 net sales of \$429 million. Fougera Pharmaceuticals operated two main businesses: Fougera, a leading player in the US dermatology generics sector with 45 products and more than 200 SKUs, and PharmaDerm, a branded specialty pharmaceuticals business with 17 brands and over 40 SKUs.

In 2012, key product launches in the US, the single largest market for Sandoz, included generic valsartan HCT (an authorized generic of the Pharmaceuticals Division's *Diovan HCT*), atorvastatin (a generic version of Pfizer's Lipitor®), voriconazole for injection (Pfizer's Vfend®), an authorized generic of sumatriptan (GlaxoSmithKline's Imitrex®) and calcipotriene (LEO Pharma's Dovonex®). Key product

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launches in various European countries include valsartan/valsartan HCT, atorvastatin (Lipitor®), candesartan (AstraZeneca's Atacand®), and irbesartan (Sanofi and Bristol-Myers Squibb's Aprovel®).

In Biopharmaceuticals, Sandoz continued to strengthen its global leadership in biosimilars, and to drive its contract manufacturing base business. Recombinant growth hormone *Omnitrope*, which was first launched in Europe in 2006 and in 2007 in the US, was launched in Colombia and Turkey in 2012, and is now marketed in over 40 countries. According to IMS data, *Omnitrope* recently became the second-largest human growth hormone in the US, outselling four of the five originator products. The rollout of high-dosage oncology formulations continued to drive growth of anemia medicine *Binocrit* in several European countries, complementing the base nephrology business. Sandoz G-CSF biosimilar, *Zarzio*, which was approved in the EU in 2009 for the treatment of neutropenia, continued to grow rapidly in Europe.

Sandoz made significant progress on its biosimilar pipeline in 2012, with the start of Phase III clinical trials for two molecules. Sandoz now has four molecules in Phase III trials, including the division's first monoclonal antibody, a biosimilar version of the originator compound rituximab (Roche's Rituxan®/MabThera®), which is currently in a Phase III clinical trial for the treatment of follicular lymphoma, and a Phase II trial for rheumatoid arthritis. The other molecules undergoing Phase III testing are biosimilar versions of pegfilgrastim (Amgen's Neulasta®), filgrastim for US registration (Amgen's Neupogen®), and epoetin alfa (Janssen's Procrit®).

In 2012, Sandoz accelerated its efforts to build a leading, sustainable and lasting presence across Sub-Saharan Africa, where it is already the number one provider of generics medicine across French West Africa. A strong product portfolio, including anti-infectives, tuberculosis treatments and maternal and child health products, support the objective to expand on the continent and address the needs of African patients. The Division also undertook close collaborations with local partners through several corporate responsibility projects, including the development of "Health Shops" in Zambia in collaboration with the Zambian Ministry of Health to improve access to essential medicines in rural areas, collaboration with Ethiopian authorities to set up a regional bioequivalence laboratory in Ethiopia, and a partnership with a local manufacturer in Cameroon to increase availability of high-quality essential drugs. Sandoz is developing plans to expand its production capacity in Sub-Saharan Africa to address a growing demand for high-quality drugs.

### **New Products**

Sandoz launched a number of important products in various countries in 2012, including:

Valsartan HCT (authorized generic of our <i>Diovan/Co-Diovan</i> )
Atorvastatin (Pfizer's Lipitor®)
Sumatriptan (GlaxoSmithKline's Imitrex®)
Candesartan/candesartan HCT (AstraZeneca's Atacand®)
Latanaprost (Pfizer's Xalatan®)
Calcipotriol (LEO Pharma's Dovonex®)
Clobetasol propionate (Gladerma Lab's Clobex®)
Donepezil (Pfizer's Aricept®)

Montelukast (Merck's Singulair ®)

Quetiapine (AstraZeneca's Seroquel®)

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# **Key Marketed Products**

The following tables describe key marketed products for Sandoz (availability varies by market):

## **Retail Generics**

Product	Originator Drug	Description
Enoxaparin sodium injection	Lovenox®	Anti-coagulant
Amoxicillin/clavulanic acid	Augmentin®	Anti-infective
Omeprazole	Prilosec®	Ulcer and heartburn treatment
Lansoprazole	Prevacid®	Proton pump inhibitor
Acetylstein	Fluimicil®	Respiratory system
Fentanyl	Duragesic®	Analgesic
Tacrolimus	Prograf®	Transplantation
Simvastatin	Zocor®	Cholestorol lowering treatment
Linex (lactobacillus)	n/a	Dietary supplement
Candesartan	Atacand®	Anti-hypertensive
Valsartan/valsartan HCT	Diovan/Co-Diovan	Cardiovascular

Anti-Infectives

Active Ingredients	Description
Oral and sterile penicillins	Anti-infectives
Oral and sterile cefalosporins	Anti-infectives
Clavulanic acid and mixtures with clavulanic acid	ß-lactam inhibitors
Classical and semisynthetic erythromycins	Anti-infectives
Tiamuline	Anti-infectives
Lovastatin, Simvastatin, Pravastatin	Statins
Vancomycin	Anti-infectives
Thyroxine	Hormones

Intermediates	Description
Various cephalosporin intermediates	Anti-infectives
Erythromycin base	Anti-infectives
Various crude compounds produced by fermentation	Cyclosporine, ascomysine, rapamycine,
	mycophenolic acid. etc.

# Biopharmaceuticals

Product	Originator Drug	Description
Omnitrope	Somatropin®	Recombinant human growth hormone
Binocrit and Epoetin alfa Hexal	Eprex®/Erypo®	Recombinant protein used for anemia
Zarzio and Filgrastim Hexal	Neupogen®	Recombinant protein used in oncology
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### Oncology Injectables

<b>Originator Drug</b>	Description
Paraplatin®	Ovarian, lung, head-neck and cervix
	cancer
Farmorubicin®	Breast, lung, ovarian, gastric and bladder
	cancer, and others
Gemzar®	Bladder, pancreas, lung, ovarian, and
	breast cancer
Folex®, Rheumatrex®	Arthritis; breast, lung, cervix and ovarian
	cancer, and others
Eloxatin®	Colorectal and colon cancer
Taxol®	Breast, lung and ovarian cancer, Kaposi
	sarcoma
Taxotere®	Breast, ovarian and non-small cell lung
	cancer
	Paraplatin® Farmorubicin® Gemzar® Folex®, Rheumatrex® Eloxatin® Taxol®

### **Principal Markets**

The two largest generics markets in the world the US and Europe are the principal markets for Sandoz, although Sandoz sells products in more than 140 countries. This table sets forth aggregate 2012 net sales by region:

Sandoz	2012 Net Sales to third parties		
	\$ millions	%	
United States	2,786	32.0	
Americas (except the United States)	634	7.3	
Europe	4,225	48.6	
Rest of the World	1,057	12.1	
Total	8,702	100.0	

	\$ millions	%
Established Markets*	6,402	73.6
Emerging Growth Markets*	2,300	26.4
Total	8,702	100.0

Many Sandoz products are used for chronic conditions that require patients to consume the product over long periods of time, from months to years. Sales of our anti-infective products are subject to seasonal variation. Sales of the vast majority of our other products are not subject to material changes in seasonal demand.

### **Production**

The goal of our supply chain strategy is to produce and distribute high-quality products efficiently. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials.

<sup>&</sup>quot;Established Markets" are US, Canada, Western Europe, Australia, New Zealand and Japan. "Emerging Growth Markets" are all other markets.

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We manufacture and package our Sandoz products at 45 manufacturing sites across 19 countries. Among these, our principal production facilities are located in Barleben, Germany; Kundl and Unterach, Austria; Menges and Ljubljana, Slovenia; Broomfield, Colorado; Wilson, North Carolina; Stryków, Poland; Kalwe and Mahad, India; Boucherville, Canada; Cambé, Brazil; Gebze and Syntex, Turkey; Hicksville and Melville, New York. In December 2010, Novartis announced the signing of a Memorandum of Understanding, confirming its intention to build a new, full-scale pharmaceutical manufacturing plant in St. Petersburg, Russia. Construction began in 2011 and the plant is expected to produce approximately 1.5 billion units per year (oral solid dosage forms), of which the majority is anticipated to be generic products. Our total investment in the plant is expected to be approximately \$140 million.

Active pharmaceutical ingredients are manufactured in our own facilities or purchased from third-party suppliers. We maintain state-of-the-art and cost-competitive processes within our own production network. Those processes include fermentation, chemical syntheses and precipitation processes, such as sterile processing. Many follow-on biologics are manufactured using recombinant DNA derived technology by which a gene is introduced into a host cell, which then produces the human protein. This manufacturing process requires sophisticated technical expertise. We are constantly working to improve current and to develop new manufacturing processes.

Where possible, our policy is to maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers, and competitive material sourcing can be assured. However, our ability to do so may at times be limited by regulatory or other requirements. We monitor market developments that could have an adverse effect on the supply of essential active pharmaceutical ingredients. All active pharmaceutical ingredients we purchase must comply with high quality standards.

We obtain agricultural, chemical and other raw materials from suppliers around the world. The raw materials we purchase are generally subject to market price fluctuations. We seek to avoid these fluctuations, where possible, through the use of long-term supply contracts. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials. All raw materials we purchase must comply with our quality standards.

For some products and raw materials, we may also rely on a single source of supply.

In November 2011, we received a Warning Letter from the FDA with respect to three of our Sandoz Division's facilities in Broomfield, Colorado, Wilson, North Carolina, and Boucherville, Canada. The letter followed inspections at all three sites in the course of 2011, and raised concerns regarding these facilities' compliance with FDA cGMP regulations. The FDA observations in the letter related primarily to general documentation, validation and investigation practices. It states that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending applications or supplements listing Novartis affiliates as a drug manufacturer. In addition, FDA may refuse requests to issue export certificates to our Sandoz US affiliate, or import certificates to our Sandoz Canada affiliates. The letter further states that other federal agencies may take the Warning Letter into account when considering the award of contracts. Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet highest quality standards. In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site. Nonetheless, if we fail to fully resolve the issues raised in the Warning Letter then we could be subject to legal action without further notice including, without limitation, seizure and injunction.

Our Sandoz Division has experienced significant supply interruptions in the past, and there can be no assurance that supply will not be interrupted again in the future as a result of unforeseen circumstances. The manufacture of our products is complex and heavily regulated, making supply never an absolute certainty. If we or our third-party suppliers fail to comply fully with regulations then there could be a product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of business interruptions or other

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unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

### **Marketing and Sales**

Sandoz sells a broad portfolio of generic pharmaceutical products to wholesalers, pharmacies, hospitals and other healthcare outlets. Sandoz adapts its marketing and sales approach to local decision making processes, depending on the structure of the market in each country.

In response to rising healthcare costs, many governments and private medical care providers, such as health maintenance organizations, have instituted reimbursement schemes that favor the substitution of bioequivalent generic products for patented pharmaceutical products. In the US, statutes have been enacted by virtually all states that permit or require pharmacists to substitute a less expensive generic product for the brand-name version of a drug that has been prescribed to a patient. Generic use is growing in Europe, but penetration rates in many EU countries are below those in the US because reimbursement practices do not create efficient incentives for substitution. Legislative or regulatory changes can have a significant impact on our business in a country. In Germany, for example, the generic market is in transition as healthcare reforms increasingly shift decision making from physicians to insurance funds. A new German Pharmaceutical Law (AMNOG), introduced in January 2011, has driven implementation of the "single-molecule" tender contract system by promoting automatic substitution at pharmacy level. In January 2012 the second part of AMNOG came into force changing the drug price ordinance for prescription-only drugs. As a consequence of the new regulation, as of January 1, 2012, pharmacies' costs of purchasing medicines significantly increased. In anticipation of the change, there was an industry-wide stock-in of products by pharmacists at the end of 2011, which impacted Sandoz sales in the first quarter of 2012.

Our Anti-Infectives business supplies Retail Generics and the pharmaceutical industry worldwide with active pharmaceutical ingredients and intermediates, mainly in the field of antibiotics.

Our Biopharmaceuticals business operates in an emerging business environment. Regulatory pathways for approving biosimilar products are either relatively new or still in development, and policies have not yet been fully defined or implemented for the automatic substitution and reimbursement of biosimilars in many markets, including the US. As a result, in many of these markets, including the US, our biosimilar products are marketed as branded competitors to the originator products.

### Competition

The market for generic products is characterized by increasing demand for high-quality pharmaceuticals that can be marketed at lower costs due to comparatively minimal initial research and development investments. Increasing pressure on healthcare expenditures and numerous patent and data exclusivity period expirations have created a favorable market environment for the generics industry. This positive market trend, however, brings increased competition among the companies selling generic pharmaceutical products, leading to ongoing price pressure on generic pharmaceuticals.

In addition, research-based pharmaceutical companies have responded to increased competition from generic products by licensing their patented products to generic companies (the so-called "authorized generic"). By doing so, research-based pharmaceutical companies participate in the conversion of their patented product once generic conversion begins. Consequently, generic companies that were not in a position to compete on a specific product may enter the generic market using the innovator's product. In the US, the authorized generic is not subject to the US Hatch-Waxman Act rules regarding exclusivity (See "Regulation"). The company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder. While this may serve as a business opportunity to Sandoz when our Pharmaceuticals Division's products lose patent protection, this tends to reduce the value of the exclusivity for the company that invested in creating the first generic medicine to

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compete with the originator product. Furthermore, certain research-based companies continually seek new ways to protect their market franchise and to decrease the impact of generic competition. For example, some research-based pharmaceutical companies have reacted to generic competition by decreasing the prices of their patented product, or engaging in other tactics to preserve the sales of their branded products, thus possibly limiting the profit that the generic companies can earn on the competing generic product.

### **Development and Registration**

Before a generic pharmaceutical may be marketed, intensive technical as well as clinical development work must be performed to demonstrate, in bio-availability studies, the bio-equivalency of the generic product to the reference product. Nevertheless, research and development costs associated with generic pharmaceuticals generally are much lower than those of the originator pharmaceuticals, as no clinical trials on dose finding and efficacy must be performed by the generic company. As a result, pharmaceutical products for which the patent and data exclusivity period has expired can be offered for sale at prices often much lower than those of products protected by patents and data exclusivity, which must recoup substantial basic research and development costs through higher prices over the life of the product's patent and data exclusivity period.

For follow-on biologic products, the regulatory pathways for approving such products are still in development, or pending final implementation, in many countries outside Europe. However, at least for certain biopharmaceutical products, a certain number of carefully targeted clinical trials in patients to determine safety and efficacy do appear to be required. Sandoz has successfully registered and launched the first biosimilar (or biosimilar type) product in Europe, the US, Canada, Japan, Taiwan, Australia and several Latin American countries, as well as two further products in Europe.

Currently, the affiliates of the Sandoz Division employ more than 2,600 Development and Registration staff who explore alternative routes for the manufacture of known compounds and develop innovative dosage forms of well-established medicines. These associates are based worldwide, including major facilities in Holzkirchen and Rudolstadt, Germany; Kundl, Schaftenau and Unterach, Austria; Ljubljana and Menges, Slovenia; Kalwe, India; Boucherville, Canada; and East Hanover, New Jersey. In 2012, Sandoz expensed \$695 million (on a core basis \$749 million, as a result, in part, of a decrease of a contingent consideration liability related to a business combination) in product development, which amounted to 8.0% of the division's net sales. Sandoz expensed \$640 million (on a core basis \$724 million, as a result, in part, of a decrease of a contingent consideration liability related to a business combination) and \$658 million (on a core basis \$618 million) in 2011 and 2010 respectively.

## Regulation

The Hatch-Waxman Act in the US (and similar legislation in the EU and in other countries) eliminated the requirement that generic pharmaceutical manufacturers repeat the extensive clinical trials required for originator products, so long as the generic version could be shown in bioavailability studies to be of identical quality and purity, and to be therapeutically equivalent to the reference product.

In the US, the decision whether a generic pharmaceutical is bioequivalent to the original patented product is made by the FDA based on an Abbreviated New Drug Application (ANDA) filed by the generic product's manufacturer. The process typically takes nearly two years from the filing of the ANDA until FDA approval. However, delays can occur if issues arise regarding the interpretation of bioequivalence study data, labeling requirements for the generic product, or qualifying the supply of active ingredients. In addition, the Hatch-Waxman Act requires a generic manufacturer to certify in certain situations that the generic product does not infringe on any current applicable patents on the product held by the innovator, or to certify that such patents are invalid or the product is non-infringing. This certification often results in a patent infringement lawsuit being brought by the patent holder against the generic company. In the event of such a lawsuit, the Hatch-Waxman Act imposes an automatic 30-month

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delay in the approval of the generic product in order to allow the parties to resolve the intellectual property issues. For generic applicants who are the first to file their ANDA containing a certification claiming non-infringement or patent invalidity, the Hatch-Waxman Act provides those applicants with 180 days of marketing exclusivity to recoup the expense of challenging the innovator patents. However, generic applicants must launch their products within certain time frames or risk losing the marketing exclusivity that they had gained by being a first-to-file applicant.

In the EU, decisions on the granting of a marketing authorization are made either by the EMA under the Centralized Procedure, or by a single Member State under the national or decentralized procedure. See "Pharmaceuticals Regulation European Union." Companies may submit Abridged Applications for approval of a generic medicinal product based upon its "essential similarity" to a medicinal product authorized and marketed in the EU following the expiration of the product's data exclusivity period. In such cases, the generic company is able to submit its Abridged Application based on the data submitted by the medicine's innovator, without the need to conduct extensive Phase III clinical trials of its own. For all products that received a marketing authorization in the EU after late 2005, the Abridged Application can be submitted throughout the EU. However, the data submitted by the innovator in support of its application for a marketing authorization for the reference product will be protected for ten years after the first grant of marketing authorization in all Member States, and can be extended for an additional year if a further innovative indication has been authorized for that product, based on pre-clinical and clinical trials filed by the innovator that show a significant clinical benefit in comparison to the existing therapies.

### **Intellectual Property**

Wherever possible, our generic products are protected by our own patents. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents also may cover particular uses of a product, such as its use to treat a particular disease or its dosage regimen. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

We take all reasonable steps to ensure that our generic products do not infringe valid intellectual property rights held by others. Nevertheless, originating companies commonly assert patent and other intellectual property rights in an effort to delay or prevent the launch of competing generic products. As a result, we can become involved in significant litigation regarding our generic products. If we are unsuccessful in defending these suits, we could be subject to injunctions preventing us from selling our generic products, or to damages, which may be substantial.

### VACCINES AND DIAGNOSTICS

Our Vaccines and Diagnostics Division is a leader in the research, development, manufacturing and marketing of vaccines and diagnostic products used worldwide. As of December 31, 2012, the Vaccines and Diagnostics Division employed 6,391 full-time equivalent associates worldwide in 30 countries. In 2012, the Vaccines and Diagnostics Division had consolidated net sales of \$1.9 billion representing 3.3% of total Group net sales.

Novartis Vaccines' products include meningococcal, influenza, pediatric, adult and travel vaccines. Novartis Diagnostics is dedicated to increasing transfusion safety with NAT blood testing products and immunoassay reagents that detect infectious disease worldwide and through distribution of research use blood genotyping products in select markets.

The current product portfolio of our Vaccines and Diagnostics Division includes more than 20 marketed products. In addition, the division's portfolio of development projects includes more than 15 potential new products in various stages of clinical development.

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The Novartis meningococcal franchise is expected to be a cornerstone of future growth for the division. Meningococcal disease causes approximately 50,000 deaths a year globally. Because almost all cases of infection are caused by five serogroups A, B, C, W-135 and Y and the distribution of strains varies greatly over time and location, we are working to deliver vaccines with broad coverage and the potential to protect all age groups at risk.

In January 2013, *Bexsero*, the Novartis investigational Meningococcal Group B Vaccine (rDNA, component, adsorbed) received EU approval, following a positive opinion from the CHMP in November 2012. With this approval *Bexsero* becomes the first broad coverage vaccine to help prevent the leading cause of meningitis in Europe. Global incidence of meningococcal Group B disease (MenB) is estimated to be between 20,000 and 80,000 cases per year, with an approximate 10 percent fatality rate. In the UK, MenB is the cause of the majority (55%) of all meningitis and septicemia, and the cause of 96% of cases in infants. *Bexsero* has also been submitted for approval to health authorities in Canada, Brazil and Australia. We are working with health authorities in the EU to provide access to *Bexsero* as soon as possible.

*Menveo* (MenACWY-CRM), a quadrivalent conjugate vaccine for the prevention of the A, C, Y and W-135 strains of meningococcal disease, was approved in 2010 in the US for use in individuals 11-55 years old and in the EU for individuals 11 years and older. In 2011, *Menveo* gained approval for use in individuals 2-10 years old in the US, and in 2012 gained approval in the EU for individuals 2 years and older. In June 2011, the FDA accepted for review a supplemental Biologics License Application to expand the *Menveo* indication to include infants and toddlers from 2 months of age. In February 2012, Novartis received a complete response letter from the FDA with respect to this application. We plan to resubmit our application to the agency in early 2013.

Influenza vaccines are an important franchise of the division. Today, we are among the world's largest producers of influenza vaccines. Influenza vaccination is one of the most effective public health interventions, sparing millions of people from complications, including death, from this infectious disease. In November 2012, the FDA approved *Flucelvax*, the first cell-culture derived influenza vaccine approved in the US, to help protect adults 18 years and older against seasonal influenza. Cell-culture technology marks the most significant advance in influenza vaccine manufacturing in the US in more than 40 years, and is an alternative to traditional egg-based production. *Flucelvax* does not contain any preservatives, such as thimerosal, or antibiotics.

In 2012, Novartis announced that it would deliver *Fluvirin*, its seasonal influenza vaccine, to the US market and ship more than 30 million doses to US customers for the 2012/2013 season. Almost 90% of these doses were shipped by September, in time for the start of public vaccination programs. Early arrival of seasonal influenza vaccines ensures that healthcare professionals are equipped to provide the earliest possible protection against influenza.

Young children and older adults are among the most vulnerable to influenza. *Fluad*, our adjuvanted seasonal influenza vaccine, has been approved for more than a decade in Europe to enhance the immune response in older adults, helping to overcome their naturally occurring immune vulnerability and enabling effective protection against influenza.

In June 2012, Novartis was awarded a contract under the HHS Centers for Innovation in Advanced Development and Manufacturing by the US Department of Health and Human Services (HHS). Under the terms of the contract, our production facility in Holly Springs, NC will provide late-stage development and manufacturing expertise and capabilities to support HHS-driven projects, including development of new biodefense agents and rapid manufacturing response in the event of a public health emergency. In addition, Novartis remains dedicated to working with the World Health Organization and other stakeholders to support global pandemic preparedness, including affordable and equitable access to pandemic vaccines for developing countries.

In 2012, Novartis informed the WHO and other public health partners that, due to adequate supply and decreased global demand, it would cease oral polio vaccine (OPV) manufacturing by 2013. All current

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supply commitments for 2013 will be fulfilled as contracted. Novartis has been proud to have provided a significant proportion of the global supply of OPV for more than 20 years and is a longtime supporter of the Global Polio Eradication Initiative. Novartis will continue to support polio eradication and other key global immunization initiatives.

Novartis Vaccines continues to expand geographically through the 2011 completion of the acquisition of an 85% stake in the vaccines company Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd. Zhejiang Tianyuan offers marketed vaccine products in China. Novartis will collaborate with Tianyuan on strengthening its existing product portfolio and expanding its innovation capabilities. This acquisition is also expected to facilitate the introduction of additional Novartis vaccines into China where there continues to be tens of thousands of new cases of vaccine-preventable diseases each year.

The Diagnostics business maintains its market leadership in blood safety and Hepatitis C antigen manufacturing. Our *Procleix* portfolio of highly sensitive nucleic acid-based tests and automation platforms, developed in collaboration with Gen-Probe, Inc. (now owned by Hologic, Inc.) are used in markets around the world to screen donated blood for HIV-1, HIV-2, Hepatitis types B and C, and West Nile Virus.

We continue to expand our line of nucleic acid testing products in global markets through a combination of regulatory approvals and ongoing investment in new assays and next-generation automation platforms. In 2011, the company received FDA approval of *Procleix Ultrio Plus* Assay, a highly sensitive 3-in-1 assay for detection of HIV-1, Hepatitis B, and Hepatitis C viruses in donated blood. The assay, like others in the *Procleix* family, feature a unique 2-region detection of HIV Type 1 to reduce the risk of missed HIV infections in the blood supply.

In September, 2012 Novartis commercially launched the fully automated and integrated *Procleix Panther* system and *Procleix Ultrio Elite* 4-in-1 assay for detection of HIV-1, HIV-2, Hepatitis B, and Hepatitis C virus in the European Union.

The use of our NAT blood and plasma screening products continues to grow in new markets, with blood banks in China, Korea and Malaysia recently coming online with Novartis platforms.

### **Vaccines and Diagnostics Division Products**

The summary and the tables that follow describe key marketed products and potential products in development in our Vaccines and Diagnostics Division. Subject to required regulatory approvals and, in certain instances, contractual limitations, we intend to sell our marketed products throughout the world. However, our Vaccines and Diagnostics Division products are not currently available in every country. Regarding our products in development, these products and indications are in various stages of development throughout the world. For some products, the development process is ahead in the US; for others, development in one or more other countries or regions is ahead of that in the US. Due to the uncertainties associated with the development process, and due to regulatory restrictions in some countries, it may not be possible to obtain regulatory approval for any or all of the new products referred to in this Form 20-F. See "Regulation" for further information on the approval process.

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### **Key Marketed Vaccine Products**

Product	Indication	
Influenza Vaccines		
Agrippal	A surface antigen, inactivated, seasonal influenza vaccine for adults and children above six months of age.	
Fluad	A surface antigen, inactivated, seasonal influenza vaccine containing the proprietary <i>MF59</i> adjuvant for the elderly	
Fluvirin	A surface antigen, inactivated, seasonal influenza vaccine for adults and children four years of age and up	
Optaflu (EU)	Cell culture-based, surface antigen, inactivated, influenza vaccine for adults 18 years of age and up	
Flucelvax (US)	Cell culture-based surface antigen, inactivated, seasonal flu influenza vaccine indicated for those aged 18 years and older	
Meningococcal Vaccines		
Bexsero	Meningococcal Group B Vaccine [rDNA component adsorbed]	
Menjugate	Meningococcal C vaccine for children 2 months of age and up	
Menveo	Meningococcal A, C, W-135 and Y vaccine for children, adolescents and adults between 2 and 55 years of age	
Travel Vaccines		
Encepur Children Encepur		
Adults	Tick-borne encephalitis vaccine for children 1-11 years of age and for adults 12+ years of age	
Ixiaro <sup>(1)</sup>	Prophylactic vaccine against Japanese encephalitis virus	
Rabipur/Rabavert	Vaccine for rabies, which can be used before or after exposure (typically animal bites) in all age groups	
Pediatric Vaccines		
Polioral	Live, attenuated, oral poliomyelitis vaccine (Sabin) containing attenuated poliomyelitis virus types 1, 2 and 3 from birth	
Quinvaxem <sup>(2)</sup>	Fully liquid pentavalent vaccine combining antigens for protection against five childhood diseases: diphtheria, tetanus, pertussis (whooping cough), hepatitis B and Haemophilus influenzae type b for children above 6 weeks of age	

<sup>(1)</sup> In collaboration with Intercell.

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# Vaccine Key Products in Development

Project/Compound	Potential indication/ Disease area	Planned submissions	Current Phase	Status
Menveo (US, infant)	Prevention of meningococcal disease (serogroups A, C, Y and W-135) in infants and toddlers, and young children	Complete	Registration	Resubmission planned early 2013
Fluad (US)	Seasonal influenza (subunit vaccine with MF59 adjuvant)	2013	III	US Phase III study for older adults (65 years of age and older) and study in children completed
Quadrivalent Influenza Vaccine (QIV)	Seasonal influenza	≥2013	II	Phase III studies expected to start in 2013
MenABCWY	Prevention of meningococcal disease (serogroups A, B, C, Y and W-135)	≥2013	II	Phase III under evaluation
Group B streptococcus	Prevention of group B streptococcus	≥2013	II	
Staph. Aureus	Prevention of Staphylococcus aureus	≥2013	I	
TdaP	Prevention of Tetanus, Diphtheria, Pertussis	≥2013	I	

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### **Key Marketed Diagnostics Products**

Product	Product Description
Procleix Tigris System	Fully integrated and automated instrument for high-throughput batch NAT blood and plasma screening
Procleix Panther System	Fully automated NAT screening instrument for continuous load or batch processing
Procleix SP System	Fully automated liquid-handling instrument for pooling and creation of archive plates
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Procleix Ultrio Elite Assay	Highly sensitive NAT assay to detect HIV-1, HIV-2, HCV and HBV on the <i>Procleix Panther</i> platform
Procleix Ultrio Plus Assay	Highly sensitive NAT assay to detect HIV-1, HCV and HBV on the <i>Procleix Tigris</i> platform.
Procleix WNV Assay	First NAT assay approved by the FDA to detect West Nile virus in donated blood
Procleix Parvo/HAV Assay	Highly sensitive 2-in-1 NAT assay to detect Parvovirus B19 and Hepatitis A during plasma processing

# Diagnostics Key Products in Development

Therapeutic Area	Product	Product Description	Planned filing dates/ Current phase
<b>Blood Screening</b>	Dengue Assay	NAT test designed to detect the Dengue virus	Development
	Procleix Xpress System	Automated pooling and archiving solution	Development
	Procleix NAT Manager Software	Procleix data and information management system	Development
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### **Principal Markets**

The principal markets for our Vaccines and Diagnostics Division include the US and Europe. The following table sets forth the aggregate 2012 net sales of the Vaccines and Diagnostics Division by region:

Vaccines and Diagnostics	2012 Net Sales to third parties		
	\$ millions	%	
United States	746	40.2	
Americas (except the United States)	181	9.7	
Europe	658	35.4	
Rest of the World	273	14.7	
Total	1,858	100.0	

	\$ millions	%
Established Markets*	1,434	77.2
Emerging Growth Markets*	424	22.8
Total	1,858	100.0

Sales of certain vaccines, including influenza and tick borne encephalitis vaccines, are subject to seasonal variation. Sales of the majority of our other products are not subject to material changes in seasonal demand.

### **Research and Development**

In 2012, the Vaccines and Diagnostics Division expensed \$453 million (on a core basis \$429 million) in research and development, which amounted to 24.4% of the division's net sales. The Vaccines and Diagnostics Division expensed \$523 million (on a core basis \$494 million) and \$523 million (on a core basis \$506 million) in research and development in 2011 and 2010 respectively.

While research and development costs for vaccines traditionally have not been as high as for pharmaceuticals, a robust clinical program including Phase I to Phase III must be performed by the manufacturer to obtain a license for commercialization. See

"Pharmaceuticals Compounds in Development" and "Pharmaceuticals Research and Development." Similarly, our NAT blood screening

" Pharmaceuticals Compounds in Development" and " Pharmaceuticals Research and Development." Similarly, our NAT blood screening research and development efforts, which we perform in collaboration with Gen-Probe, Inc., as well as our other diagnostic research and development efforts, require extensive and expensive research and testing of potential products. At each step, there is a substantial risk that we will not achieve our goals. In such an event, we may decide or be required to abandon a product or program in which we have made a substantial investment.

#### **Production**

The goal of our supply chain strategy is to produce and distribute high quality products efficiently. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may also rely on a single source of supply.

<sup>&</sup>quot;Established Markets" are US, Canada, Western Europe, Australia, New Zealand and Japan. "Emerging Growth Markets" are all other markets.

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We manufacture our vaccines products at six facilities in Europe, the US and Asia. Our principal production facilities are located in Liverpool, UK; Marburg, Germany; Siena and Rosia, Italy; Ankleshwar, India; and Holly Springs, North Carolina. We continue to invest and upgrade our existing sites to ensure that previously initiated remediation efforts are completed and meet quality standards. In addition, certain conjugation and chemistry activities for vaccines are performed at our Emeryville, California site. At our Emeryville site we manufacture antigens and associated conjugates as both intermediates, and in final kits for diagnostics and blood donation screening around the world. We are the world leader in GMP production of HCV antigens used for clinical diagnostic and blood donation screening products sold by other companies. Companies in these markets, including our long-standing collaboration partners Ortho Clinical Diagnostics purchase these products which we manufactured for use in their blood testing assays. Our NAT products for blood and plasma screening are manufactured by Gen-Probe, Inc., with sales, marketing, and distribution by Novartis Diagnostics.

Each year new seasonal influenza vaccines need to be produced in order to help induce protection against the current circulating strains of the virus, which can change from year to year. Global surveillance of influenza viruses is conducted throughout the year by the World Health Organization (WHO) Influenza Surveillance Network, which provides information on currently circulating strains and identifies the appropriate strains to be included in next season's influenza vaccine. Each year, the EMA and the US Centers for Disease Control then confirm the vaccine composition for the coming season for the northern hemisphere and the Australian Therapeutic Goods Administration for the southern hemisphere. There can be no guarantee that the division will succeed in producing and having approved an updated flu vaccine within the timeframes necessary to commercialize the vaccine for the applicable flu season.

The manufacture of our products is complex and heavily regulated, which means that supply is never guaranteed. Like our competitors, our Vaccines and Diagnostics Division has faced significant manufacturing issues. If we or our third-party suppliers fail to comply fully with regulations then there could be a product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of such events or other unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

### Marketing and Sales

Our main Vaccines marketing and sales organizations are based in Switzerland, Germany, UK, Italy and the US. We are also seeking to expand operations in China, India, Europe and Latin America. In the US, we market influenza, meningococcal, Japanese Encephalitis and rabies vaccines through a network of wholesalers and distributors as well as direct to key customers. Direct sales efforts are focused on public health and distributor channels, and on non-traditional channels, such as employers, chain drug headquarters and service providers.

The main Diagnostics marketing and sales organizations are based in the US, Switzerland, and Hong Kong. Sales efforts for NAT products are focused on blood banks and plasma fractionators, with some marketing efforts in the US and Canada focused on sales of research-use red blood cell genotyping products from Progenika, Inc., through an agreement with Grifols SA of Spain. With about 40% of the 90 million blood donations made worldwide each year not being tested with nucleic acid screening, the company will continue to focus on increasing adoption of NAT testing in emerging markets of the world.

### Competition

The global market for products of the type sold by our Vaccines and Diagnostics Division is highly competitive, and we compete against other major international corporations with substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

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There is no guarantee that any product, even with patent protection, will remain successful if another company develops a new product offering significant improvements over existing products.

### Regulation

Our vaccines products are subject to essentially the same regulatory procedures as are the products of our Pharmaceuticals Division. See "Pharmaceuticals Regulation." In the US, a company seeking approval of a vaccine submits a Biologics License Application (BLA) for the vaccine, rather than an NDA. Subsequently, the BLA follows substantially the same path for approval as does an NDA. In addition, license applications for seasonal flu vaccines must be submitted annually.

Our diagnostics products are regulated as medical devices in the US and the EU. See " Alcon Regulation." However, in the US, for specific diagnostics products that are sold into blood banks, or sold for diagnosis of HIV-1 infection, applications are submitted for review by the FDA's Center for Biologics Evaluation and Research (CBER). Under such review, the product is considered a biologic until such time as approval is received, at which time the product becomes a medical device. For products used specifically for screening of blood donors, or biologic reagents sold for further manufacturing use, the medical device is subject to Licensure by CBER. The submission for this purpose follows the same requirements as Vaccines; a Biologic License Application is submitted to CBER. CBER usually takes 240 days to review a BLA. In the EU, Diagnostics products are specifically covered by the EU In Vitro Diagnostic (IVD) Directive. Under that Directive, certain products are subject to review and prior approval by a "notified body." Others are subject to the manufacturer self-certification process.

### **Intellectual Property**

We attach great importance to patents, trademarks, and know-how in order to protect our investment in research and development, manufacturing and marketing. It is our policy to seek the broadest possible protection for significant product developments in all major markets. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen.

The protection offered by such patents extends for varying periods depending on the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage. We monitor our competitors and vigorously challenge infringements of our intellectual property.

### **CONSUMER HEALTH**

Consumer Health is a leader in the research, development, manufacturing and marketing of a wide range of competitively differentiated products that restore, maintain or improve the health and well-being of consumers, as well as pets and livestock. The business of Consumer Health is conducted by a number of affiliated companies throughout the world. Consumer Health consists of the following two divisions:

OTC (over-the-counter medicines)

Animal Health

Each division has its own research, development, manufacturing, distribution and selling capabilities. However, neither division is material enough to the Group to be separately disclosed as a segment. As of December 31, 2012, the affiliates of Consumer Health employed 8,752 full-time equivalent associates worldwide. In 2012, the affiliates of Consumer Health achieved consolidated net sales of \$3.7 billion, which represented 6.6% of the Group's total net sales.

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The divisions of Consumer Health place considerable emphasis on the development of strong, consumer-oriented and trustworthy brands. To deliver accelerated sales growth and to achieve leadership positions in the fields in which we compete, the divisions of Consumer Health seek to give voice to the consumer and to determine the needs and desires of consumers.

In the dynamic world of consumer healthcare, consumers are becoming more knowledgeable about health and the benefits of self-medication. The success of each division depends upon its ability to anticipate and meet the needs of consumers and health professionals worldwide.

The following is a description of the two Consumer Health divisions:

OTC (over-the-counter medicines) is a leader in offering leading products designed for self-care, and the and prevention of common medical conditions and ailments, to enhance people's overall health and well-being. The business of OTC is conducted by a number of affiliated companies in more than 50 countries. The OTC business focuses on a group of strategic global brands in leading product categories that include treatments for cough/cold/respiratory (*Triaminic, Otrivin, TheraFlu/NeoCitran*), pain relief (*Excedrin, Voltaren*), digestive health (*Benefiber, Prevacid24HR, Pantoloc Control*), dermatology (*Lamisil, Fenistil*), and smoking cessation (*Habitrol/Nicotinell*).

Animal Health offers products and services to save, prolong and improve animal lives, focusing on both companion and farm animals (including cultivated fish). The business of Animal Health is conducted by affiliated companies in approximately 40 countries. Animal Health has a dedicated research and development team that benefits from synergies with other Novartis businesses, most notably research in the Pharmaceuticals Division. Key products for companion animals include *Atopica* (atopic dermatitis management), *Deramaxx* and *Onsior* (pain relief), *Fortekor* (heart failure in dogs, chronic renal insufficiency in cats), and *SentinellMilbemax/Interceptor* (intestinal parasite control and heartworm prevention), while leading farm animal products include the therapeutic anti-infective *Denagard*, an effective broad-spectrum antimicrobial used to treat and control bacteria in swine, *CLiK*, an effective insect growth regulator used to control blowfly strike in sheep, cattle vaccines used to prevent respiratory and reproductive diseases in beef and dairy cattle, and *Zolvix*, a sheep drench representing the first new sheep anthelmintic class in 25 years. Aquaculture products include vaccines and treatments mainly used in salmon farming.

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#### **Principal Markets**

The principal markets for Consumer Health are the US and Europe. The following table sets forth the aggregate 2012 net sales of Consumer Health by region:

Consumer Health	2012 Net Sales to third parties		
	\$ millions	%	
United States	652	17.4	
Americas (except the United States)	429	11.5	
Europe	1,877	50.3	
Rest of the World	777	20.8	
Total net sales	3,735	100.0	

	\$ millions	%
Established Markets*	2,415	64.7
Emerging Growth Markets*	1,320	35.3
Total net sales	3,735	100.0

"Established Markets" are US, Canada, Western Europe, Australia, New Zealand and Japan. "Emerging Growth Markets" are all other markets.

Sales of our OTC Division are marked by a high degree of seasonality, with our cough, cold and allergy brands significantly affected by the timing and severity of the annual cold and flu and allergy seasons. Sales of our Animal Health Division's livestock segment can also fluctuate seasonally, and can be significantly affected by climatic and economic conditions, or by changing health or reproduction rates of animal populations. Sales of most of our other products are not subject to material changes in seasonal demand.

### **Production**

The goal of our supply chain strategy is to produce and distribute high quality products efficiently. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may also rely on a single source of supply.

OTC: Products for our OTC Division are produced by the division's own plants, strategic third-party suppliers and other Group plants (which are predominantly owned and operated by the Pharmaceuticals Division). The primary OTC plants are located in Lincoln, Nebraska; Nyon, Switzerland; Humacao, Puerto Rico; and Jamshoro, Pakistan.

Animal Health: Approximately 80% of our production volume is manufactured by third parties and Novartis affiliates in other divisions. Animal Health has production facilities of its own located around the world, with main sites in Wusi Farm, China; Dundee, UK; Larchwood, Iowa; Charlottetown, Canada; and Huningue, France.

While production practices may vary from division to division, we generally obtain our raw materials, intermediates and active ingredients from suppliers around the world. The raw materials, intermediates and active ingredients we purchase are generally subject to market price fluctuations. We seek to avoid these fluctuations, where possible, through the use of long-term supply contracts. We also proactively

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monitor markets and developments that could have an adverse effect on the supply of essential materials. All raw materials we purchase must comply with our quality standards.

In December 2011, we suspended operations and shipments from the OTC Division facility located at Lincoln, Nebraska, which also produces certain products for our Animal Health Division. This action was taken to accelerate maintenance and other improvement activities at the site. Subsequently, in January 2012, we recalled certain OTC Division products that were produced at the Lincoln facility. We made significant progress in 2012 in the remediation of quality issues at Lincoln, and have out-sourced the production of certain Lincoln products. However, as of the date of this Form 20-F, it is not possible to determine when the plant will resume significant operations. As a result of the manufacturing issues at Lincoln, we have suffered and may continue to suffer significant losses in sales and market share. In addition, we have been required to expend considerable resources on the remediation of the issues at this site. Should we fail to complete the planned improvements at the site in agreement with FDA in a timely manner, then we may suffer a significant additional losses in sales and drainage of resources, and we could be subject to legal action without further notice.

As a result of the activities at Lincoln, Consumer Health has experienced, and continues to experience, significant supply interruptions, and there can be no assurance that supply will not be interrupted again in the future as a result of unforeseen circumstances. The manufacture of our products is complex and heavily regulated, which means that supply is never guaranteed. If we or our third-party suppliers fail to comply fully with regulations then there could be another product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of business interruptions or other unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

### Marketing and Sales

OTC: OTC aims to be a leading global participant in fulfilling the needs of patients and consumers for self-medication healthcare. Strong, leading brands and products, innovation led by a worldwide research and development organization, and in-house marketing and sales organizations are key strengths in pursuing this objective. We engage in general public relations activities, including media advertisements, brand websites and other direct advertisements of brands, to the extent permitted by law in each country. We distribute our products through various channels such as pharmacies, food, drug and mass retail outlets.

Animal Health: Animal Health's products are mostly prescription-only treatments for both farm and companion animals. The major distribution channel is veterinarians, either directly or through wholesalers of veterinary products. Primary marketing efforts are targeted at veterinarians using such marketing tools as targeted personal selling, printed materials, direct mail, advertisements, articles in the veterinary specialty press, and conferences and educational events for veterinarians. In addition, we engage in general public relations activities and media advertising, including brand websites and other direct advertisements of brands, to the extent permitted by law in each country.

### Competition

The global market for products of the type sold by Consumer Health is highly competitive, and we compete against other major international corporations with substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development. Particularly in the US, our branded OTC products compete against "store brand" products that are made with the same active ingredients as ours. These products do not carry our trusted brand names, but they also do not carry the burden of the expensive advertising and marketing which helped to establish a demand for the product. As a result, the store brands may be sold at lower prices. In recent

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years, consumers have increasingly begun to purchase store brand OTC products instead of branded products.

### **Research and Development**

OTC: At OTC, the focus of research and development activities is primarily on analgesics, cough/cold/respiratory and digestive health treatments. OTC also works closely with the Pharmaceuticals Division to evaluate appropriate products that can be switched from prescription to OTC status. The development of line extensions to leverage brand equities is also of high importance. These extensions can take many forms including new flavors, new galenical forms and more consumer-friendly packaging.

Animal Health: Novartis Animal Health has dedicated research and development facilities in Switzerland, North America and Australia. The main focus for research is identification of potential new parasiticides and therapeutics in key areas of internal medicine. In addition, in the US and Canada, we devote resources to the quest for new pharmaceuticals and vaccines for farm animals and cultivated fish. Also, our researchers exploit synergy with other Novartis businesses and collaborate with external partners to develop veterinary therapeutics and vaccines. Drug delivery projects, some in collaboration with external partners, concentrate on key treatment areas and aim to improve efficacy and ease of use.

In 2012, Consumer Health expensed \$291 million (on a core basis \$291 million) in research and development, which amounted to 7.8% of the division's net sales. Consumer Health expensed \$296 million (on a core basis \$292 million) and \$261 million (on a core basis \$261 million) in research and development in 2011 and 2010 respectively.

### Regulation

OTC: For OTC products, the primary regulatory process for bringing a product to market consists of preparing and filing a detailed dossier with the appropriate national or international registration authority and obtaining approval of the applicable health authority. See "Pharmaceuticals Regulation." In the US, in addition to the NDA process, which also is used to approve prescription pharmaceutical products, an OTC product may be sold if the FDA has determined that the product's active ingredient is generally recognized as safe and effective. FDA makes this determination through a regulatory process known as the OTC Drug Review. In the OTC Drug Review, the FDA has established, in a series of monographs, the conditions under which particular active ingredients may be recognized as safe and effective for OTC use. Pharmaceutical companies can market products containing these active ingredients without the necessity of filing an NDA and going through its formal approval process, so long as the company complies with the terms of the published monograph. Outside the US, countries have their own regulatory processes for approving or allowing the sale of pharmaceutical products, including prescription, OTC, and switching from prescription to OTC status. These processes vary from country to country, but essentially are all built on the principle of requiring an assessment of product efficacy, quality and safety before any marketing activities can be undertaken. In addition, a process similar to the US monograph system exists in some countries, such as Canada and Japan.

Animal Health: The registration procedures for animal medicines are similar to those for human medicines. An animal drug application for product registration must be accompanied by extensive data on target animal and user safety, environmental fate and toxicology, efficacy in laboratory and clinical studies, information on manufacturing, quality control and labeling as well as on residues and food safety if applied to food-producing animals. In the US, animal health products are generally regulated by the FDA's Center for Veterinary Medicine. Certain product categories are regulated by the Environmental Protection Agency, and vaccines are under the control of the US Department of Agriculture. In the EU, veterinary medicinal products need marketing authorization from the competent authority of a member-state (national authorization) or from the EU Commission (community authorization) following either the Centralized Procedure, Mutual Recognition Procedure or the Decentralized Procedure. See "Pharmaceuticals Regulation."

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### **Intellectual Property**

Our Consumer Health divisions are strongly brand-oriented. As a result, we consider our trademarks to be of utmost value. Enforceable trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative.

Wherever possible our products are protected by patents. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

Our Consumer Health divisions also sell products which are not currently covered by patents. Some of these products have never been patent-protected and others have lost protection due to patent expiry.

### 4.C Organizational Structure

See "Item 4. Information on the Company 4.A History and Development of Novartis," and "Item 4. Information on the Company 4.B Business Overview Overview."

### 4.D Property, Plants and Equipment

Location/Division

Our principal executive offices are located in Basel, Switzerland. Our divisions and business units operate through a number of affiliates having offices, research facilities and production sites throughout the world.

We generally own our facilities. However, some sites are leased under long-term leases. Some of our principal facilities are subject to mortgages and other security interests granted to secure indebtedness to certain financial institutions. We believe that our production plants and research facilities are well maintained and generally adequate to meet our needs for the foreseeable future.

Ciza of Cita (in square meters)

Major Activity

The following table sets forth our major production and research facilities.

Location/Division	Size of Site (in square meters)	Major Activity
Major Production facilities:		
Pharmaceuticals		
Ringaskiddy, Ireland	60,000	Drug substances, intermediates
Grimsby, UK	64,000	Drug substances, intermediates
Stein, Switzerland	130,000	Steriles, ampules, vials, tablets, capsules, transdermals
Basel, Switzerland Klybeck	11,000	Drug substances, intermediates

Basel, Switzerland Schweizerhalle 26,000

Drug substances, intermediates

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Location/Division	Size of Site (in square meters)	Major Activity
Basel, Switzerland St. Johann	28,000	Drug substances, intermediates, biopharmaceutical drug substance
Torre, Italy	24,000	Tablets, drug substance intermediates
Changshu, China	56,000	Drug substances, intermediates
Vacaville, California	7,400	Biopharmaceutical drug substances
Suffern, NY	48,000	Tablets, capsules, transdermals, vials
Kurtkoy, Turkey	52,000	Tablets, capsules, effervescents
Horsham, UK	17,000	Tablets, capsules
Sasayama, Japan	8,600	Tablets, capsules, dry syrups, suppositories, creams, powders
Huningue, France	44,000	Biopharmaceutical drug substances
Cairo, Egypt	47,000	Tablets, creams, liquids, steriles
Singapore	29,000	Bulk tablets
Wehr, Germany	24,000	Tablets, creams, ointments
Barbera, Spain	24,000	Tablets, capsules
Resende, Brazil	16,000	Drug substances, intermediates
Chang Ping, China	17,000	Tablets, capsules, gel
Schaftenau, Austria	5,600	Tablets
San Carlos, California	21,000	Inhalors
Carlsbad, California	15,500	Molecular Diagnostics testing and services, Clinical trial assay center

# Alcon

Fort Worth, TX	421,000 (production and R&D facilities)	Pharmaceutical
Puurs, Belgium	55,000	Pharmaceutical, Surgical, Vision Care
Singapore	50,000	Pharmaceutical, Vision Care
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Location/Division	Size of Site (in square meters)	Major Activity
Duluth, GA	44,000 (production and R&D facilities)	Vision Care
Grosswallstadt, Germany	40,000 (production and R&D facilities)	Vision Care
Houston, Texas	36,325	Surgical
Johor, Malaysia	35,000	Vision Care
Pulau Batam, Indonesia	27,000	Vision Care
Des Plaines, IL	27,000	Vision Care
Huntington, West Virginia	24,600	Surgical
Irvine, California	19,500 (production and R&D facilities)	Surgical
Sinking Spring, Pennsylvania	18,000	Surgical
Mississauga, Canada	15,000	Vision Care
Kaysersberg, France	14,800	Pharmaceutical, Vision Care
Cork, Ireland	13,650	Surgical
Sao Paulo, Brazil	8,360	Pharmaceutical, Vision Care
Erlangen, Germany	6,600 (production and R&D facilities)	Surgical
Aliso Viejo, California	5,200	Surgical
Schaffhausen, Switzerland	4,100 (production and R&D facilities)	Surgical
Mexico City, Mexico	2,900	Pharmaceutical, Vision Care
Pressath, Germany	2,600 (production and R&D facilities)	Surgical
Neve Ilan, Israel	1,000	Surgical
Sandoz		
Kundl and Schaftenau, Austria	449,000 (production and R&D facilities)	Biotech products, intermediates, active drug substances, final steps (finished pharmaceuticals)
Menges, Slovenia	131,000 (production and R&D facilities)	Biotech products and active drug substances
Hicksville, NY	101,700 (production and R&D facilities)	Dermatology products
Barleben, Germany	95,000	Broad range of finished dosage forms

Ljubljana, Slovenia

83,000 (production and R&D facilities)

Broad range of finished dosage forms

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Location/Division	Size of Site (in square meters)	Major Activity
Broomfield, CO	60,000	Broad range of finished dosage forms
Kalwe, India	61,000	Broad range of finished dosage forms
Mahad, India	43,000	Active drug substances
Gebze, Turkey	42,000	Broad range of finished dosage forms
Cambé, Brazil	32,000	Broad range of finished dosage forms
Wilson, NC	31,000	Broad range of finished dosage forms
Rudolstadt, Germany	37,000 (production and R&D facilities)	Inhalation technology, ophthalmics and nasal products
Stryków, Poland	20,000	Broad range of finished dosage forms
Holzkirchen, Germany	17,000 (production and R&D facilities)	Oral dispersible films, transdermal delivery systems, reservoir and matrix patches
Melville, NY	15,800 (production and R&D facilities)	Dermatology products
Unterach, Austria	15,000 (production and R&D facilities)	Oncology injectables
Boucherville, Canada	14,000 (production and R&D facilities)	Injectable products
Kolshet, India	11,000	Generic pharmaceuticals
Vaccines and Diagnostics		
Holly Springs, NC	50,000 (production facilities)	Vaccines and adjuvant
Emeryville, CA	99,000 (production and R&D facilities; includes Pharmaceuticals facilities)	Vaccines and blood testing
Siena/Rosia, Italy	99,000 (production and R&D facilities)	Vaccines
Liverpool, UK	38,000	Vaccines
Marburg, Germany	86,000 (production and R&D facilities)	Vaccines and adjuvant
Ankleshwar, India	11,000	Vaccines

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Location/Division	Size of Site (in square meters)	Major Activity
Consumer Health OTC		
Lincoln, NE	48,000 (production and R&D facilities)	Tablets, liquids, creams, ointments, capsules, patches, powders
Nyon, Switzerland	15,000 (production and R&D facilities)	Liquids, creams, aerosols
Humacao, Puerto Rico	13,000	Tablets, capsules, medicated chocolates, softgels and medicated dissolving strips
Jamshoro, Pakistan	24,000	Tablets, liquids, creams
Animal Health		
Wusi Farm, China	39,000	Insecticides, antibacterials, acaricides, powders
Larchwood, IA	13,000 (production and R&D facilities)	Veterinary immunologicals
Dundee, UK	11,000	Liquids
Huningue, France	5,000	Formulation and packaging of tablets, creams, ointments, suspensions and liquids
Charlottetown, Canada	5,000	Veterinary vaccines for aquaculture
Major Research and Development Facilities:		
Pharmaceuticals		
East Hanover, NJ	177,000	General pharmaceutical products
Basel, Switzerland St. Johann	150,000	General pharmaceutical products
Basel, Switzerland Klybeck	140,000	General pharmaceutical products
Cambridge, MA	116,000	General pharmaceutical products
Horsham, UK	38,000	Respiratory and nervous system diseases
Emeryville, CA		Oncology

(included in Vaccines and Diagnostics facilities)

Shanghai, China 5,000 Oncology

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Location/Division	Size of Site (in square meters)	Major Activity
Alcon		
Fort Worth, TX	421,000 (production and R&D)	Pharmaceutical
Duluth, GA	44,000 (production and R&D)	Vision Care
Barcelona, Spain	41,250	Pharmaceutical, Vision Care
Grosswallstadt, Germany	40,000 (production and R&D)	Vision Care
Irvine, California	19,500 (production and R&D)	Surgical
Erlangen, Germany	6,600 (production and R&D)	Surgical
Schaffhausen, Switzerland	4,100 (production and R&D)	Surgical
Pressath, Germany	2,600 (production and R&D)	Surgical
Sandoz		
Kundl and Schaftenau, Austria	449,000 (production and R&D facilities)	Biotech processes, pharmaceutical technologies
Menges, Slovenia	131,000 (production and R&D facilities)	Biotech products and active drug substances
Hicksville, NY	101,700 (production and R&D facilities)	Dermatology products
Ljubljana, Slovenia	83,000 (production and R&D facilities)	Broad range of oral sterile finished dosage forms and new delivery systems
Rudolstadt, Germany	37,000 (production and R&D facilities)	Finished dosage forms for inhalation and ophthalmics
Kolshet, India	20,000 (production and R&D facilities)	Generic pharmaceuticals
Holzkirchen, Germany	17,000 (production and R&D facilities)	Broad range of dosage forms, including implants and transdermal therapeutic systems
Melville, NY	15,800 (production and R&D facilities)	Dermatology products
Unterach, Austria	15,000 (production and R&D facilities)	Oncology injectables
Boucherville, Canada	14,000 (production and R&D facilities)	Injectable and ophthalmic products
East Hanover, NJ	6,000	Broad range of finished dosage forms

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Location/Division	Size of Site (in square meters)	Major Activity
Vaccines and Diagnostics		
Emeryville, CA	99,000 (production and R&D facilities; includes Pharmaceuticals facilities)	Vaccines and blood testing
Siena/Rosia, Italy	97,000 (production and R&D facilities)	Vaccines
Marburg, Germany	45,000 (production and R&D facilities)	Vaccines
Cambridge, MA	9,000	Vaccines
Consumer Health OTC		
Lincoln, NE	48,000 (production and R&D facilities)	Tablets, capsules, liquids, ointments, creams and high-potent compounds, powders
Nyon, Switzerland	15,000 (production and R&D facilities)	Over-the-counter medicine products
Hyderabad, India	3,000 (R&D facilities)	Tablets, capsules, powders, creams, ointments, oral liquids, multiparticulates
Animal Health		
St. Aubin, Switzerland	26,000	Parasiticides, therapeutics for companion and farm animals
Larchwood, IA	13,000 (production and R&D facilities)	Veterinary vaccines
Yarrandoo, Australia	3,000	Animal Health products
Victoria, Canada	4,500	Aquaculture vaccines
Basel, Switzerland	2,000	Animal Health products

In the fourth quarter of 2010, we announced a Group-wide review of our manufacturing footprint. In 2012 we continued to optimize our manufacturing footprint, bringing the total number of production sites that are in the process of being restructured or divested to 15. This has and is expected to enable us to reduce excess capacity and to shift strategic product to technology competence centers. We have recorded charges related to exits, impairment charges and inventory write-offs of \$68 million in 2012, bringing the total charges to \$400 million since the program began.

The current phase of the long-term redevelopment of our St. Johann headquarters site in Basel, Switzerland is expected to be finalized in 2015. This project, called "Campus," was started in 2001 with the aim of transforming the site into a center of knowledge with a primary emphasis on international corporate functions and research activities. At that time, changes needed to be made to the Campus, since the site had originally been designed primarily for pharmaceuticals production, but Research and Development had come to account for a greater proportion of our activities at the site. Through December 31, 2012, the total amount paid and committed to be paid on the Campus Project was

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\$2.1 billion. We expect that, through 2015, we will spend more than \$2.3 billion on the Campus and to transfer production facilities from the Campus to other sites in the Basel region. Preparations for plans beyond 2015 are currently under discussion. We intend to fund these expenditures from internally developed resources.

In 2007, NIBR opened a start-up facility for our new R&D center in Shanghai, China (CNIBR). In 2008, we broke ground on Phase 1 of a new facility that was originally to be home to approximately 400 R&D scientists and approximately 400 other Pharmaceuticals Division personnel. In 2009, we announced that we would expand the scope of the site and invest \$1 billion over the next five years to increase the size of our operations in Shanghai. Based on a re-evaluation of the site conducted in 2010, the current Phase 1 has been extended by two buildings to fulfill the requirements for the cross-divisional Shanghai campus to house 800 offices and 400 laboratory work places. As of December 31, 2012, structural works have been finished at CNIBR, and the first above ground buildings have begun to be built. Through December 31, 2012, the total amount paid and committed to be paid on the CNIBR Project is \$345 million.

In 2010, we announced that we would invest \$600 million over the next five years to build new laboratory and office space for NIBR in Cambridge, Massachusetts on an area of land close to the existing NIBR research facilities on Massachusetts Avenue. In 2011 we finalized design plans for the new buildings, received necessary zoning changes from the city of Cambridge and began preparing the site for construction. Construction began on the site in April 2012. Through December 31, 2012, the total amount paid and committed to be paid on the NIBR Project is \$164 million.

In the fourth quarter of 2012, we announced the planned construction of a new state-of-the-art biotechnology production site in Singapore with an investment valued at over \$500 million. The new facility will focus on drug substance manufacturing based on cell culture technology. Construction is planned to commence in 2013, and the site is expected to be fully operational in 2016. It will be co-located with the pharmaceutical production site based in Tuas, Singapore. In the future, Singapore is expected to be a technological competence center for both biotechnology and pharmaceutical manufacturing at Novartis. Commencement of construction at the site is planned for 2013. Through December 31, 2012, the total amount paid and committed to be paid on this project is \$22.5 million.

In the second quarter of 2012, Novartis announced the construction of a new state-of-the-art production facility to produce solid dosage form medicines for the Pharmaceuticals Division in Stein, Switzerland. We expect our investment in this facility to exceed CHF 500 million. The new facility is planned to replace an older facility which will be partially demolished by 2016. Stein is planned to be a technological competence center for both sterile and solid dosage form drugs, while Novartis plans to expand the site's strategic role as a key platform for global launches of new pharmaceutical products. Through December 31, 2012, the total amount paid and committed to be paid on this project is \$90 million.

During 2012, the Pharmaceuticals Division commenced a series of projects in which we expect to invest over \$300 million over the next five years. These projects are in the following three areas: implementation of a serialization product tracking program across its pharmaceutical operations network, providing a health, safety and environment/Good Manufacturing Practices upgrade for its milling and blending center at Stein, Switzerland, and for the upgrade of change control systems.

In 2010, we commenced a construction project on the campus of Novartis Pharmaceuticals Corporation (NPC) in East Hanover, New Jersey. This project is expected to continue through 2013. It involves construction of three new office buildings, a parking garage, and upgrades to the site entrances. The purpose of the project is to consolidate NPC personnel on one site to drive innovation, collaboration and productivity. The consolidation is also expected to achieve long-term cost savings resulting from the elimination of off-campus leases. We expect that through 2013 we will spend more than \$545 million to complete the construction and consolidate operations onto the campus. As of December 31, 2012, the total amount paid and committed to be paid on this project was \$442 million.

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In December 2012, we acquired a 16,000 square meter FDA-approved manufacturing facility in Morris Plains, NJ, from Dendreon Corporation for \$43 million. In particular, we purchased all fixed assets at the site, including all equipment, machinery, utilities, and cell therapy related plant infrastructure, while the land and building will continue to be leased from a third party. The facility, and certain former Dendreon personnel whom we intend to retain, will support both clinical and commercial production of potential new products and therapies that emerge from the Novartis-University of Pennsylvania (Penn) collaboration announced in August 2012, including CTL019. The facility space and infrastructure could also accommodate future chimeric antigen receptor production activities, in addition to CTL019.

In 2008, the Vaccines and Diagnostics Division broke ground on a new rabies and tick-borne encephalitis manufacturing facility in Marburg, Germany which is expected to require a total investment of approximately \$330 million. Construction is complete and the facility is in the process of executing the necessary validation activities. Regulatory approvals for products are planned for 2012 and 2013. As of December 31, 2012, the total amount paid and committed to be paid on this project was \$303 million.

In 2009, the Vaccines and Diagnostics Division opened the division's new cell culture-based influenza vaccine manufacturing site in Holly Springs, North Carolina. As of December 31, 2012, the total amount spent on the project was \$426 million, net of grants reimbursed by the US government. The total investment in this new facility is expected to be least \$900 million, partly supported by grants from the US government and prior investments in flu cell culture technologies at the Novartis Vaccines site in Marburg, Germany.

The Vaccines and Diagnostics Division has commenced a project for a new vaccine manufacturing facility in Recife, Brazil. The manufacturing plant is part of Novartis Vaccines' strategy to enter the Brazilian market, and is aligned with the government's goal to become self-sufficient in vaccine production. Our total investment in the facility is expected to be approximately \$475 million. The technical start up of the facility is planned for approximately 2015. As of December 31, 2012, the total amount paid and committed to be paid on this project was \$23 million.

In 2010, Novartis announced the signing of a Memorandum of Understanding, confirming its intention to build a new full-scale pharmaceutical manufacturing plant in St. Petersburg, Russia. In June 2011 we announced the commencement of construction. The plant is expected to produce approximately 1.5 billion units per year (oral solid dosage forms), of which the majority is anticipated to be generic products. Product registration for production at the site is expected to begin in 2014. Our total investment in the plant is expected to be approximately \$140 million. As of December 31, 2012, the total amount paid and committed to be paid on this project was \$30 million.

In 2012, the Alcon Division began the expansion of its Duluth, Georgia facility for contact lens manufacturing. The capital cost for the expansion is expected to be \$250 million, and production is scheduled to begin at the site in September 2013. Construction will add 6,500 square meters to the existing facility, and is expected to take place over the next three to five years. As of December 31, 2012, the total amount paid and committed to be paid on this project is \$78.3 million.

In June 2012, the Alcon Division announced the expansion of its Irvine, California operations to increase capabilities in the areas of pharmaceutical development and clinical trials. Alcon signed an 11-year lease for three buildings, covering 17,000 square meters, which are expected to open in early 2013. As of December 31, 2012, the total amount paid and committed to be paid on this project is \$10.5 million.

### **Environmental Matters**

We integrate core values of environmental protection into our business strategy to add value to the business, manage risk and enhance our reputation.

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We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, use and disposal of materials, including the discharge of pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment which could cause environmental or property damage or personal injuries, and which could require remediation of contaminated soil and groundwater. Under certain laws, we may be required to remediate contamination at third party sites, or at certain of our properties regardless of whether the contamination was caused by us, or by previous occupants of the property.

See also "Item 3. Key Information Item 3.D Risk Factors Environmental liabilities may impact our results of operations" and "Item 18. Financial Statements note 20."

#### Item 4A. Unresolved Staff Comments

Not applicable.

### Item 5. Operating and Financial Review and Prospects

### 5.A Operating Results

This operating and financial review should be read together with the Group's consolidated financial statements in this Annual Report, which have been prepared in accordance with International Financial Reporting Standards (IFRS) as published by the International Accounting Standards Board.

#### **OVERVIEW**

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our focused, diversified portfolio of businesses is made up of six global operating divisions and reports its results in five segments:

Pharmaceuticals: Innovative patent-protected prescription medicines

Alcon: Surgical, ophthalmic pharmaceutical and vision care products

Sandoz: Generic pharmaceuticals

Vaccines and Diagnostics: Human vaccines and blood-testing diagnostics

Consumer Health: OTC (over-the-counter medicines) and Animal Health

The Group established its newest and second largest division, Alcon, after securing 100% ownership of Alcon, Inc., on April 8, 2011. The new division includes the CIBA Vision contact lens and lens care business and selected ophthalmic medicines from the Pharmaceuticals Division and is a world leader in eye care, offering the widest spectrum of innovative surgical, pharmaceutical and vision care products to address the world?s eye care needs.

Novartis has leadership positions in each of the five businesses, giving us the capacity to address customer and patient needs across segments of the healthcare marketplace. We believe that our ability to innovate in all these segments will allow us to tailor our portfolio in response to market opportunities and will enable Novartis to continue as an industry leader.

Headquartered in Basel, Switzerland, the Novartis Group companies employed approximately 128,000 full-time equivalent associates as of December 31, 2012, with operations in more than 140 countries around the world.

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### **BUSINESS AND OPERATING ENVIRONMENT**

### **Opportunity and Risk Summary**

Our financial results are affected, to varying degrees, by the following external factors.

### Transformational changes fueling demand

**Aging population and shifting behaviors:** The aging of the world population, as well as the increasing prevalence of obesity and other unhealthy lifestyle factors, is driving demand for treatments that address conditions disproportionately afflicting the elderly as well as other chronic diseases.

**Rise in healthcare spending:** The global healthcare market continues to grow, led by emerging economies, where access and demand for healthcare are expanding.

**Scientific advances:** Personalized medicine is opening new opportunities for targeted therapies, helping improve patient outcomes and reduce costs.

**New technologies:** Social and mobile technologies are facilitating the delivery of care and enhancing communication with patients, providers and payors.

**Shift to generics and over-the-counter products:** Faced with rising healthcare costs, governments around the world are encouraging consumers to substitute generics for patented pharmaceuticals. Consumers, too, are shifting to over-the-counter products in an effort to keep costs down.

### Increasingly Challenging Business Environment

**Patent expirations and generic competition:** The loss of market exclusivity and the introduction of generic competitors can significantly erode sales of our innovative products.

**Regulatory and safety hurdles:** The costs associated with bringing a drug to market have increased as a result of heightened regulatory requirements. Even after a drug is approved, there is a possibility that safety events could occur and materially affect our results.

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

**Financial crisis:** As challenges from the 2008 financial crisis continue to affect the global economy, governments and patients worldwide are seeking to minimize healthcare costs.

**Legal proceedings:** There is a trend of increasing government investigations and litigations against companies in the healthcare industry. Despite our best efforts to comply with the laws of the approximately 140 countries in which we sell products, any failure in compliance could have a material adverse effect on our business and reputation.

For more detail on these trends and how they impact our results, see "Factors Affecting Results of Operations" below.

### **Novartis Structure**

The Novartis Group strategy for sustainable, long-term growth is based on focused diversification, in which we seek to access multiple, growing segments of the healthcare market. Reflecting our leadership positions across these segments, the Group's businesses are divided on a worldwide basis into six global operating divisions, which report results in five segments (Pharmaceuticals, Alcon, Sandoz, Vaccines and Diagnostics, and Consumer Health), and Corporate activities. Except for Consumer Health, which

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comprises two divisions (Over-the-Counter, or OTC, and Animal Health) that are not material enough to the Group to be reported on an individual basis, these segments reflect the Group's internal management structure and are disclosed separately because they research, develop, manufacture, distribute and sell distinct products that require different marketing strategies.

#### **Pharmaceuticals**

Pharmaceuticals researches, develops, manufactures, distributes and sells patented prescription medicines and is organized in the following business franchises: Oncology; Primary Care, consisting of Primary Care medicines and Established Medicines; and Specialty Care, consisting of Ophthalmology, Neuroscience, Integrated Hospital Care, and Critical Care medicines. Novartis Oncology is organized as a business unit, responsible for the global development and marketing of oncology products.

Pharmaceuticals is the largest contributor among the segments, and in 2012 accounted for \$32.2 billion, or 57%, of Group net sales and \$9.6 billion, or 81%, of Group operating income (excluding Corporate Income and Expense, net).

#### Alcon

As the global leader in eye care, Alcon researches, develops, manufactures, distributes and sells eye care products and technologies to serve the full life cycle of eye care needs. Alcon offers a broad range of products to treat many eye diseases and conditions, and is organized into three businesses: Surgical, Ophthalmic Pharmaceuticals and Vision Care.

The Surgical portfolio includes technologies and devices for cataract, retinal, glaucoma and refractive surgery, as well as intraocular lenses to treat cataracts and refractive errors, like presbyopia and astigmatism. Alcon also provides viscoelastics, surgical solutions, surgical packs, and other disposable products for cataract and vitreoretinal surgery. In Ophthalmic Pharmaceuticals, the portfolio covers treatment options for elevated intraocular pressure caused by glaucoma, anti-infectives to aid in the treatment of bacterial infections and bacterial conjunctivitis, and ophthalmic solutions to treat inflammation and pain associated with ocular surgery. The Ophthalmic Pharmaceuticals product portfolio also includes eye and nasal allergy treatments, as well as over-the-counter dry eye relief and ocular vitamins. Daily disposable, monthly replacement, and color-enhancing contact lenses, as well as a complete line of contact lens care products including multi-purpose and hydrogen-peroxide based solutions, rewetting drops, and daily protein removers, comprise the portfolio in Vision Care.

In 2012, Alcon accounted for \$10.2 billion, or 18%, of Group net sales, and \$1.5 billion, or 12%, of Group operating income (excluding Corporate Income and Expense, net).

#### Sandoz.

Sandoz develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical and biotechnological active substances, which are not protected by valid and enforceable third-party patents. Sandoz has activities in Retail Generics, Anti-Infectives, Biopharmaceuticals, Oncology Injectables, Ophthalmics, Respiratory and Dermatology. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and sells biotechnology manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market. Sandoz Ophthalmics, which was formed through the integration of Falcon, Alcon's generic division, develops, manufactures and markets generic ophthalmic and otic products. In addition, Sandoz is active in Respiratory following its acquisition of Oriel Therapeutics in 2010, and

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expanded its presence in Dermatology through the acquisition of specialty dermatology company Fougera Pharmaceuticals, Inc. in 2012.

In 2012, Sandoz accounted for \$8.7 billion, or 15%, of Group net sales and \$1.1 billion, or 9% of Group operating income (excluding Corporate Income and Expense, net).

### Vaccines and Diagnostics

Vaccines and Diagnostics researches, develops, manufactures, distributes and sells preventive human vaccines and novel blood-screening diagnostic tools, which help protect the world's blood supply by preventing the spread of infectious diseases.

In 2012, Vaccines and Diagnostics accounted for \$1.9 billion, or 3%, of Group net sales and generated an operating loss of \$250 million.

#### Consumer Health

Consumer Health consists of two divisions: OTC and Animal Health. Each has its own research, development, manufacturing, distribution and selling capabilities, but neither is material enough to the Group to be separately disclosed as a segment. OTC offers readily-available consumer medicine, and Animal Health provides veterinary products for farm and companion animals.

In 2012, Consumer Health accounted for \$3.7 billion, or 7%, of Group net sales and \$48 million, or slightly below 1%, of Group operating income (excluding Corporate Income and Expense, net).

### **Corporate**

Corporate activities include certain functions such as Financial Reporting & Accounting, Treasury, Internal Audit, IT, Legal, Tax and Investor Relations that are managed at the Corporate level and provide support to the organization but are not attributable to specific divisions. Corporate also includes the costs of our headquarters and corporate coordination functions in major countries.

### NOVARTIS STRATEGY FOR SUSTAINABLE GROWTH

As the only healthcare company globally with leading positions in pharmaceuticals, eye care, generics, vaccines and diagnostics, over-the-counter medicines and animal health, we believe that Novartis is uniquely positioned to capture growth opportunities across the healthcare marketplace and to mitigate the impact of challenges in particular sectors.

### Our Priorities: Innovation, Growth and Productivity

Our strategy, which is based on the focused diversification of our healthcare portfolio, requires a consistent focus on three core priorities: (1) extending our lead in innovation through the research and development of new offerings and the expansion of applications for existing offerings; (2) accelerating growth with new launches and a greater presence in Emerging Growth Markets; and (3) enhancing productivity through efficiency initiatives that free up resources for reinvestment and shareholder returns.

### Extending Our Lead in Innovation

We believe that innovation is a competitive advantage for Novartis. In 2012, we maintained our investment in R&D as a percentage of sales at the upper level for our industry. Our Pharmaceuticals Division, for example, invested 21% of net sales in innovation.

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(1)

Benefiting from our continued focus on innovation, Novartis has one of the industry's most competitive pipelines, delivering the highest number of new molecular entities (NMEs) between 2007 and 2011, according to Credit Suisse. As of the end of 2012, the Novartis Institutes for BioMedical Research (NIBR, our global pharmaceutical research organization whose costs are allocated to the Pharmaceuticals and Alcon divisions) had 92 NMEs in research and exploratory development prior to proof-of-concept (POC) determination. In 2012, NIBR delivered 12 positive POC studies, which we use to get an early read on a drug's safety and effectiveness.

Number of pre-POC NMEs from NIBR<sup>(1)</sup>

NMEs in research and exploratory development prior to proof-of-concept (POC) determination.

Since its integration into the Novartis Group, Alcon has leveraged NIBR to gain access to a range of technologies, from biologics to structural biology and high throughput screening, that previously were only available to it through external partners. With expanded R&D capabilities, Alcon has prioritized glaucoma and macular degeneration in drug discovery efforts.

Sandoz also continues to innovate in the fast-growing biosimilars segment, where it is the global leader with three marketed products. With Phase III clinical trials for epoetin alfa (biosimilar Epogen®/Procrit®) and rituximab (biosimilar Rituxan®/Mabthera®) underway, Sandoz continued to advance its biosimilars pipeline in 2012.

In Vaccines and Diagnostics, we achieved important pipeline milestones in 2012, including a positive European Committee for Medicinal Products for Human Use (CHMP) opinion for *Bexsero*, our meningococcal serogroup B vaccine, for use in children over two months old, followed by EU approval in January 2013, and FDA approval for *Flucelvax*, the first cell-culture vaccine to help protect against seasonal influenza in the United States.

In terms of advancing innovative products through clinical trials, Novartis has a probability of success that is five times the industry median from 2007 to 2011, as calculated by biopharmaceutical benchmarking company KMR. Benefitting from our strength in this area, our robust pipeline has helped to rejuvenate our portfolio. For example, in 2012, our Pharmaceuticals Division received 11 approvals for innovative medicines and new indications in the United States and European Union, including EMA and FDA approval for *Afinitor* (everolimus) in combination with exemestane as a treatment for postmenopausal women with a specific type of advanced breast cancer, which affects approximately 220 000 women each year. These approvals, which were based on Phase III trial data showing that *Afinitor* plus exemestane more than doubled the time women with the HR+/HER2- type of advanced breast

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cancer lived without tumor growth, marks the first major breakthrough in the treatment of this disease in 15 years.

#### Focus: Results of R&D investments in Pharmaceuticals

71 NMEs in post-POC clinical development

138 projects in clinical development

GenMed: 87 Pharmaceuticals projects (46 NMEs)

Oncology: 51 projects (25 NMEs)

11 major approvals achieved in the US and EU including:

Afinitor (HR+/HER2- breast cancer) US and EU

Afinitor/Votubia (TSC angiomyolipomas) US and EU

Seebri (COPD) EU

Jakavi (myelofibrosis) EU

Signifor (Cushing's disease) EU

Certican (liver transplantation) EU

### Accelerating Growth Across Six Divisions

Building on our strength in innovation, Novartis seeks to drive growth across the portfolio by working to deliver new treatments quickly and efficiently to customers and patients in need. Since an increasing proportion of these customers and patients are found in emerging markets where demand for and access to healthcare are rising, Novartis continues to strengthen its presence in these fast-growing markets.

In 2012, innovative products continued to make a major contribution to the Group's overall performance, with recently launched products (products launched since 2007, except Sandoz products launched in last 24 months) generating \$16.3 billion or 29% of total net sales. These products, which include *Gilenya*, *Lucentis*, *Tasigna* and *Afinitor*, grew 13% over the previous year.

Emerging Growth Markets, which we define as all markets except the United States, Canada, Western Europe, Australia, New Zealand and Japan, were also a key contributor to growth in 2012, contributing \$13.8 billion or 24% of total net sales. We also committed \$500 million in 2012 to build a new state-of-the-art biotechnology production site in Singapore, which offers a wide range of advantages due to its strong local biomedical presence and knowledge, skilled labor, and proximity to growth markets in Asia. We expect this facility will significantly expand our footprint in this high-growth region.

### **Enhancing Productivity**

Novartis continually seeks to operate as efficiently as possible to reduce costs and enhance margins, in order to provide flexibility to invest for the future and increase returns to shareholders. Ongoing productivity initiatives relate to procurement and resource allocation across the

portfolio, as well as our manufacturing network and supporting infrastructure.

We have made our Procurement function an important source of savings. By leveraging our scale, implementing global category management and creating country Centers of Excellence in key markets, we generated annual savings of approximately \$1.3 billion in 2012.

We continued to optimize our Marketing & Sales function by reallocating resources and streamlining processes while investing in new launches for growth brands. In Pharmaceuticals, Marketing & Sales

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expenses in constant currencies decreased as a percentage of net sales to 26.6% for 2012 from 27.5% in 2011.

We also continued to optimize our manufacturing footprint in 2012 as part of a Group-wide review we initiated in 2010. The review has two aims: first, to establish a worldwide manufacturing network of technology Centers of Excellence, and second, to optimize the cost structure across divisions and enhance utilization rates at strategic sites to 80% of capacity. As of the end of 2012, we have 15 production sites in the process of being restructured or divested.

Lastly, with Alcon fully integrated as the second largest division in the Novartis Group portfolio, we realized merger-related cost synergies of approximately \$370 million cumulatively, achieving our initial savings target one year ahead of time.

Taken together, our productivity initiatives allowed us to exceed our annual productivity target of 3.5 to 4.0% of net sales.

#### RESULTS OF OPERATIONS

In evaluating the Group's performance, we consider not only the IFRS results, but also additional non-IFRS measures, in particular core results and constant currency results. These measures assist us in evaluating our ongoing performance from year to year and we believe this additional information is useful to investors in understanding our business.

The Group's core results exclude the amortization of intangible assets, impairment charges, expenses relating to the integration of acquisitions as well as other items that are, or are expected to accumulate within the year to be, over a \$25 million threshold that management deems exceptional. For a reconciliation between IFRS results and core results, see "Core Results" below.

We present information about our revenue and various values and components relating to operating income and net income in constant currencies (cc). We calculate constant currency net sales and operating income measures by applying the prior-year average exchange rates to current financial data expressed in non-US dollars in order to estimate an elimination of the impact of foreign exchange rate movements.

These non-IFRS measures are explained in more detail below, see "non-IFRS measures as defined by Novartis" and are not intended to be substitutes for the equivalent measures of financial performance prepared in accordance with IFRS. These measures may differ from similarly titled non-IFRS measures of other companies.

**2012 Compared to 2011** 

# **Key Figures**

	Year ended Dec 31, 2012 \$ m	Year ended Dec 31, 2011 \$ m	Change in \$	Change in constant currencies
Net sales	56,673	58,566	(3)	0
Other revenues	888	809	10	11
Cost of goods sold	(18,756)	(18,983)	(1)	2
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Gross profit	38,805	40,392	(4)	(1)
Marketing & Sales	(14,353)	(15,079)	(5)	(1)
Research & Development	(9,332)	(9,583)	(3)	0
General & Administration	(2,937)	(2,970)	(1)	3
Other income	1,187	1,354	(12)	(6)
Other expense	(1,859)	(3,116)	(40)	(37)
Operating income	11,511	10,998	5	8
Income from associated companies	552	528	5	5
Interest expense	(724)	(751)	(4)	(1)
Other financial income and expense	(96)	(2)	nm	nm
-				
Income before taxes	11,243	10,773	4	7
Taxes	(1,625)	(1,528)	6	8
	, , ,			
Net income	9,618	9,245	4	7
Tee meome	>,010	>, <b>=</b> :0	•	,
Attributable to:				
Shareholders of Novartis AG	9,505	9,113	4	8
Non-controlling interests	113	132	(14)	(14)
Basic earnings per share	3.93	3.83	3	6
Free cash flow	11,383	12,503	(9)	
	,	, , ,	. ,	

nm = not meaningful

# **Core Key Figures**

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Core gross profit	41,847	43,839	(5)	(2)
Marketing & Sales	(14,352)	(15,077)	(5)	(1)
Research & Development	(9,116)	(9,239)	(1)	2
General & Administration	(2,923)	(2,957)	(1)	3
Other income	813	443	84	100
Other expense	(1,109)	(1,100)	1	9
Core operating income	15,160	15,909	(5)	(2)
Core net income	12,811	13,490	(5)	(3)
Core basic earnings per share	5.25	5.57	(6)	(3)

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### **Group Overview**

Net sales amounted to \$56.7 billion (-3%, 0% cc), as growth in recently launched products (products launched since 2007, except Sandoz products launched in last 24 months) absorbed patent expiries. Currency depressed results by 3 percentage points as a result of the strengthening of the dollar against most currencies.

Across the Group's diversified healthcare portfolio, recently launched products continued to perform strongly and in 2012 comprised 29% of Group net sales, up from 25% a year ago.

Operating income increased 5% (+8% cc) to \$11.5 billion. The strengthening of the US dollar resulted in a negative currency impact of 3 percentage points. Cost of goods sold decreased by 1% (+2% cc) to \$18.8 billion in 2012, but represented an increase of 0.7 percentage points to 33.1% of net sales. This led to a reduction in the gross margin by 0.5 percentage points (cc) to 68.5%. Marketing & Sales expenses decreased 5% (-1% cc) to \$14.4 billion, improving 0.4 percentage points to 25.3% of net sales, as productivity improvements and changes in the portfolio mix were partly offset by investments in new launch products. R&D expenses decreased by 3% (0% cc) in 2012 to \$9.3 billion. This included \$109 million in impairments of intangible assets. General & Administration expenses decreased by 1% (+3% cc) to \$2.9 billion. Other income was down 12% (-6% cc) to \$1.2 billion and largely consisted of a *Tekturna/Rasilez* provision reduction, divestment gains and restructuring provision releases. Other expense was down 40% (-37% cc) to \$1.9 billion and included acquisition-related charges and restructuring costs.

In 2012, the adjustments made to Group operating income to arrive at core operating income amounted to \$3.6 billion (2011: \$4.9 billion). These adjustments included the amortization of intangible assets of \$2.9 billion (2011: \$3.0 billion) and exceptional net expense of \$773 million (2011: \$1.9 billion).

The significant exceptional expense items, net, in 2012 were \$149 million for a United States restructuring in Pharmaceuticals and \$265 million of Alcon integration costs, which were offset by exceptional gains of \$472 million. The previous year benefited from exceptional product divestment and other gains of \$1.0 billion, offset by a number of exceptional expense items totaling \$2.9 billion, principally the *Tekturna/Rasilez*-related impairment and other charges of \$903 million, restructuring charges of \$487 million and a legal settlement of \$204 million.

Core operating income, which excludes exceptional items and amortization of intangible assets, decreased 5% (-2% cc) to \$15.2 billion. Core operating income margin in constant currencies decreased by 0.7 percentage points. A positive currency impact of 0.2 percentage points resulted in a core operating income margin of 26.7% of net sales.

Net income increased 4% (+7% cc) to \$9.6 billion following the increase in operating income. EPS increased 3% (+6% cc) to \$3.93 from \$3.83 in the prior year.

Core net income was down 5% (-3% cc) to \$12.8 billion, in line with core operating income. Core EPS declined 6% (-3% cc) to \$5.25.

Free cash flow of \$11.4 billion was \$1.1 billion lower than the prior year mainly on account of higher investments in property, plant and equipment as well as in intangible and other non-current assets and lower proceeds from the sale of non-current assets which amounted to \$0.5 billion in the current period compared to \$0.8 billion in the previous year.

### **Net Sales by Segment**

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Pharmaceuticals	32,153	32,508	(1)	2
Alcon	10,225	9,958	3	5
Sandoz	8,702	9,473	(8)	(4)
Vaccines and Diagnostics	1,858	1,996	(7)	(4)
Consumer Health	3,735	4,631	(19)	(16)
Net sales	56,673	58,566	(3)	0

	Year ended Dec 31, 2012 \$ m	Year ended Dec 31, 2011	Change in \$ %	Change in constant currencies %
Established Markets*	42,834	44,774	(4)	(2)
<b>Emerging Growth Markets*</b>	13,839	13,792	0	6
Net Sales	56,673	58,566	(3)	0

Emerging Growth Markets are all markets other than the Established Markets of the US, Canada, Japan, Australia, New Zealand and Western Europe.

## **Pharmaceuticals**

Net sales were \$32.2 billion (-1%, +2% cc), driven by 8 percentage points of volume growth, partially offset in constant currencies by the negative impact of generic competition (\$1.9 billion, -6 percentage points) and slightly negative pricing. Recently launched major products (products launched since 2007, including *Lucentis, Tasigna, Exjade, Sebivo/Tyzeka, Exforge, Galvus, Aclasta/Reclast, Cubicin, Exelon* Patch, *Afinitor/Votubia, Tekturna/Rasilez, Onbrez, Gilenya, Fanapt* and *Ilaris*) contributed \$11.4 billion or 35% of net sales for the division, compared to 28% in 2011.

Regionally, Europe (\$10.2 billion, -5% cc) saw a strong performance of recently launched products but was impacted by generic competition, mainly for *Diovan*, and by negative price effects. Performance in the United States (\$10.4 billion, +4% cc) benefited from robust growth for *Tasigna*, *Gilenya* and *Afinitor*, and was only partly impacted by generic competition to *Diovan* (\$2.1 billion, -11% cc), as no generic competitor to *Diovan* mono-substance was approved in the United States by the end of 2012 (while the combination product, *Diovan HCT*, faced competition from a single generic competitor holding 180-day exclusivity and from Sandoz with an authorized generic). Japan's performance (\$4.0 billion, +3% cc) improved versus 2011 due to new launches which more than offset the biennial price cut. Latin America and Canada (\$3.1 billion, +9% cc) achieved strong growth rates fueled by new product launches despite the *Diovan* generic impact in Canada. Emerging Growth Markets (\$7.4 billion, +6% cc) were driven by double-digit growth in China and India.

#### TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2012

Brands	Business franchise	Indication	States		world	Change in constant currencies		Change co	rrencies
			\$ m	%	\$ m	%	\$ m	%	%
Gleevec/Glivec	Oncology	Chronic myeloid leukemia	1,698		2,977	\ /	4,675	0	4
Diovan/Co Diovan	Primary care	Hypertension	2,087	(11)	2,330	(28)	4,417	(22)	(21)
		Age-related macular							
Lucentis	Ophthalmics	degeneration			2,398		2,398	17	22
Sandostatin	Oncology	Acromegaly	649		863		1,512	5	8
Exforge	Primary care	Hypertension	358	10	994	18	1,352	12	16
Zometa	Oncology	Cancer complications	561	. ,	727	(10)	1,288	(13)	(11)
Gilenya	Neuroscience	Relapsing multiple sclerosis	727	90	468	nm	1,195	142	147
Exelon/Exelon									
Patch	Neuroscience	Alzheimer's disease	428	14	622	(4)	1,050	(2)	2
Tasigna	Oncology	Chronic myeloid leukemia	351		647	( - )	998	39	44
Galvus	Primary care	Diabetes	551	20	910		910	34	43
Exjade	Oncology	Iron chelator	251	(3)	619		870	2	7
Ziljuut	Integrated	non enclacor	201	(5)	01)		0.0	_	•
Neoral/Sandimmun	Hospital Care	Transplantation	64	(10)	757	(6)	821	(9)	(6)
Afinitor/Votubia	Oncology	Breast cancer	412	( - )	385	(-)	797	80	85
J	2,								
Voltaren (excl.	Additional	T (1)		(7.5)	7.50		==0	(4)	0
OTC)	products	Inflammation/pain	1	(75)	758	1	759	(4)	0
D I .// I .	Established		254	(0)	224		<b>5</b> 00	(4)	(2)
Reclast/Aclasta	medicines	Osteoporosis	354	(8)	236	9	590	(4)	(2)
** 0	Integrated		220	•	2.40			- 4	
Myfortic	Hospital Care	Transplantation	239	20	340	14	579	12	16
	Additional	Attention deficit/							_
Ritalin/Focalin	products	hyperactivity disorder	402		152		554	1	3
Comtan/Stalevo	Neuroscience	Parkinson's disease	147	(31)	383		530	(14)	(11)
Xolair	Critical Care	Asthma			504		504	5	12
Femara	Oncology	Breast cancer	22	(90)	416	(37)	438	(52)	(50)
Top 20 products total			8,751	6	17,486	3	26,237	0	4
Rest of portfolio			1,641	(3)	4,275	(5)	5,916	(7)	(4)
*							•		- 1
Total Division sales			10,392	4	21,761	. 1	32,153	(1)	2
Total Division sales			10,392	4	21,701	1	32,133	(1)	4

nm = not meaningful

### Pharmaceuticals Division Product Highlights Leading Products

Net sales growth data below refer to 2012 worldwide performance. Growth rates are not provided for some recently launched products since they are not meaningful.

Gleevec/Glivec (\$4.7 billion, +4% cc) continued to grow as a treatment for adult patients with metastatic and/or unresectable KIT+ gastrointestinal stromal tumors (GIST), as an adjuvant treatment for certain adult patients following resection of KIT+ GIST, and as a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). Our Bcr-Abl franchise, which consists of Gleevec/Glivec and Tasigna, grew strongly in 2012, reaching net sales of \$5.7 billion (+9% cc).

Diovan Group (\$4.4 billion, -21% cc), consisting of mono-substance Diovan and combination product Diovan HCT, saw worldwide sales decline due to the loss of exclusivity of both products in the European Union, Canada and the United States. Performance was sustained in key Emerging Growth Markets such as China, as well as select countries in Latin America, Asia Pacific, Middle East and Africa.

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Lucentis (\$2.4 billion, +22% cc) grew strongly as the only anti-VEGF therapy licensed in many countries for three ocular indications: wet age-related macular degeneration (wet AMD), visual impairment due to diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO). In wet AMD, Lucentis is approved in more than 100 countries and individualized treatment consistent with its EU label is the standard of care. Lucentis is approved for the treatment of visual impairment due to DME and visual impairment due to macular edema secondary to RVO in more than 80 countries. In September and October of 2012, we filed regulatory submissions in the European Union and Japan for Lucentis as a treatment for visual impairment due to choroidal neovascularization secondary to pathological myopia. Genentech/Roche holds the rights to Lucentis in the United States.

Sandostatin (\$1.5 billion, +8% cc), a somatostatin analogue used as a treatment for patients with functional gastroenteropancreatic tumors as well as acromegaly, continued to benefit from increasing use of Sandostatin LAR in key markets. A new presentation of Sandostatin LAR, which includes an enhanced diluent, safety needle and vial adapter, has been approved in 26 countries to date with additional filings underway. Sandostatin is also approved in more than 39 countries for the delay of disease progression in patients with advanced neuroendocrine tumors of the midgut or unknown primary tumor location.

Exforge Group (\$1.4 billion, +16% cc), which includes Exforge and Exforge HCT, continued to grow at a solid double-digit rate, fueled by continued demand in the United States, Asia Pacific and Middle East, as well as ongoing Exforge HCT launches in Asia and Latin America. Exforge delivered double-digit growth globally and is now available for patients in more than 100 countries. Exforge HCT, which consists of Exforge with a diuretic in a single pill, is now available in over 60 countries.

Zometa (\$1.3 billion, -11% cc), which is used in an oncology setting to reduce or delay skeletal-related events in patients with bone metastases from solid tumors and multiple myeloma, declined as anticipated in 2012 due to competition.

Gilenya (\$1.2 billion, +147% cc) continued to show rapid growth as the first once-daily oral therapy approved for relapsing remitting and/or relapsing forms of multiple sclerosis (MS and RRMS) in adult patients, and achieved blockbuster status in 2012 with \$1.2 billion in annual sales. Gilenya is indicated in the United States for relapsing forms of MS, and in the European Union for adult patients with highly active RRMS, defined as either high disease activity despite treatment with beta interferon, or rapidly evolving severe RRMS. As of December 2012, there are approximately 56,000 patients who have been treated with Gilenya in clinical trials and in a post-marketing setting, and approximately 62,000 patient years of exposure. In April 2012, following completion of their safety reviews, the FDA and EMA both confirmed the positive benefit-risk profile of Gilenya when used in accordance with updated product information, which for both regions includes additional requirements (such as blood pressure monitoring and electrocardiograms) for the existing six-hour observation period following the first dose and more specific guidance on patient selection parameters to aid in the identification of patients suitable for Gilenya treatment. In particular situations, it is recommended that the first dose monitoring period be extended. Gilenya is currently approved in over 65 countries around the world, and is licensed from Mitsubishi Tanabe Pharma Corporation.

Exelon/Exelon Patch (\$1.1 billion, +2% cc) combined sales increased slightly in 2012 as a therapy for mild-to-moderate forms of Alzheimer's disease dementia as well as dementia linked with Parkinson's disease. Exelon Patch, the novel transdermal form of the medicine launched in 2007 and now available in more than 80 countries worldwide, generated the majority of the sales. In August 2012, the FDA approved a higher dose of Exelon Patch for the treatment of people with mild-to-moderate Alzheimer's disease and mild to moderate Parkinson's disease dementia. In November 2012, CHMP issued a positive opinion for the approval of the higher dose of Exelon Patch for the treatment of patients with mild-to-moderately severe Alzheimer's disease in Europe.

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Tasigna (\$1.0 billion, +44% cc) grew rapidly as a more effective, targeted therapy for certain adult patients with Ph+ CML. It is currently approved as first-line therapy for newly diagnosed patients with Ph+ CML in the chronic phase in more than 80 countries globally, including the United States, European Union, Japan and Switzerland, with additional submissions pending worldwide. Tasigna is also approved in more than 100 countries as a second-line treatment for patients with Ph+ CML in chronic and/or accelerated phase who are resistant or intolerant to existing treatment, such as Gleevec/Glivec. Tasigna market share continues to rise in both the first-line and second-line settings. This product is part of our Bcr-Abl franchise with net sales of \$5.7 billion, (+9% cc), which also includes Gleevec/Glivec.

Galvus Group (\$910 million, +43% cc), which includes Galvus (vildagliptin), an oral treatment for type 2 diabetes, and Eucreas, a single-pill combination of vildagliptin and metformin, delivered strong growth in key markets, particularly in Europe, Japan, Latin America and Asia Pacific. Performance was driven by a continued focus on patients whose diabetes remains uncontrolled on metformin, as well as an expansion of usage in new patient segments based on new indications. Galvus is currently approved in more than 100 countries. Eucreas was the first single-pill combining a DPP-4 inhibitor and metformin to be launched in Europe and is currently approved in more than 85 countries.

Exjade (\$870 million, +7% cc), a once-daily oral therapy for blood transfusion iron overload approved in more than 100 countries, saw steady sales growth as a decline in the United States was more than offset by growth in Europe, Latin America, Canada and Japan. Worldwide regulatory filings are underway and the EMA has approved Exjade as a treatment for patients with non-transfusion-dependent thalassemia syndromes, a diverse group of genetic disorders that cause anemia, with a first approval achieved in Canada.

Neoral/Sandimmun (\$821 million, -6% cc), an immunosuppressant primarily used to prevent organ rejection following a kidney, liver or heart transplant, experienced only modestly declining sales, despite ongoing generic competition, due to its pharmacokinetic profile, reliability and use in treating a life-threatening condition. Neoral is also approved for use in lung transplant patients in many countries outside the United States, and is also indicated for treatment of select autoimmune disorders such as psoriasis and rheumatoid arthritis. Neoral is marketed in approximately 100 countries.

Afinitor/Votubia (\$797 million, +85% cc), an oral inhibitor of the mTOR pathway, accelerated its strong growth trajectory in 2012 following FDA and EMA approvals in HR+/HER2- advanced breast cancer. Everolimus, the active ingredient in Afinitor/Votubia, was also approved in the United States as Afinitor and in the European Union as Votubia for the treatment of adult patients with renal angiomyolipomas and subependymal giant cell astrocytomas (SEGAs) associated with tuberous sclerosis complex who do not require immediate surgery. The FDA also granted approval for a new formulation, Afinitor Disperz tablets, for patients with SEGAs. Afinitor/Votubia is now approved in five indications in the United States and four in the European Union. Everolimus is available under the trade names Zortress/Certican for use in other non-oncology indications and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Voltaren/Cataflam (\$759 million, 0% cc), a leading non-steroidal anti-inflammatory drug available in more than 140 countries, saw stable sales as competition was offset by continued growth in regions such as Latin America, the Middle East, Africa and Asia based on long-term trust in the brand. Indicated for the relief of symptoms in rheumatic diseases like rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions, Voltaren/Cataflam is marketed by the Pharmaceuticals Division in a wide variety of dosage forms. In addition, in various countries, our OTC Division markets low-dose oral forms and the topical therapy of Voltaren as over-the-counter products.

*ReclastlAclasta* (\$590 million, -2% cc), a once-yearly bisphosphonate infusion for the treatment of certain forms of osteoporosis and Paget's disease of the bone, saw sales decline slightly in 2012. Sold as *Reclast* in the United States and *Aclasta* in the rest of the world, the product is approved in more than 100 countries for up to six indications. It is also the only bisphosphonate approved to reduce the incidence of

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fractures at all three key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. Zoledronic acid, the active ingredient in *Reclast/Aclasta*, is also approved in a number of countries in a different dosage under the trade name *Zometa* for certain oncology indications.

*Myfortic* (\$579 million, +16% cc), a transplantation medicine, continued to grow as a treatment for the prevention of acute rejection of kidney allografts. It is approved for this indication, in combination with cyclosporine and corticosteroids, in more than 90 countries.

Ritalin/Focalin (\$554 million, +3% cc) continued to grow as a treatment for attention deficit hyperactivity disorder (ADHD) in children. Ritalin and Ritalin LA are available in more than 70 and 30 countries, respectively, and are also indicated for narcolepsy. Focalin and Focalin XR are available in the United States, and Focalin XR, which is additionally indicated for adults, is also approved in Switzerland. Immediate release Focalin is subject to generic competition.

Comtan/Stalevo (\$530 million, -11% cc), indicated for the treatment of Parkinson's disease, saw sales decline in 2012 due to generic competition in some markets. Stalevo (carbidopa, levodopa and entacapone) is indicated for certain Parkinson's disease patients who experience end-of-dose motor fluctuations, known as "wearing off". Stalevo is available in more than 50 countries. Comtan (entacapone) is also indicated for the treatment of Parkinson's disease patients who experience end-of-dose wearing off and is marketed in approximately 50 countries. Both products are marketed by Novartis under a licensing agreement with the Orion Corporation.

Xolair (\$504 million, +12% cc), a biologic drug for severe persistent allergic asthma in Europe and moderate-to-severe persistent allergic asthma in the United States, is now approved in more than 90 countries and continued to grow strongly in Europe, Japan, Canada and Latin America. Novartis co-promotes Xolair with Genentech/Roche in the United States and shares a portion of operating income, but does not book United States sales. A Phase III trial is progressing to support registration in China. Omalizumab, the active ingredient in Xolair, is also in Phase III development for the treatment of a debilitating skin disease called chronic idiopathic urticaria, with regulatory filing planned in 2013.

Femara (\$438 million, -50% cc), a treatment for early stage and advanced breast cancer in postmenopausal women, experienced a decline in sales due to multiple generic entries in the United States, Europe and other key markets.

## Other Products of Significance

Tekturna/Rasilez (\$383 million, -29% cc) sales declined following label updates in the European Union, United States and Japan. The label updates followed our decision in December 2011 to halt the ALTITUDE study. Patient safety is the highest priority for Novartis and we are sharing the end-of-treatment results which confirmed the preliminary findings with health authorities worldwide as required. Novartis voluntarily ceased to market *Valturna*, a single-pill combination containing aliskiren and valsartan, in the United States as of July 2012.

TOBI (\$317 million, +9% cc) sales, including both TOBI nebulizer solution and TOBI Podhaler formulations of the antibiotic tobramycin, continued to grow with TOBI Podhaler capturing 13% of total sales in 2012. Both products are used for the management of Pseudomonas aeruginosa infection in cystic fibrosis patients aged six years and older. TOBI Podhaler, approved in the European Union, Canada, Switzerland and other countries can be delivered using a portable, pocket-sized inhaler that reduces administration time by approximately 70% relative to TOBI. In the United States, Novartis has responded to the FDA's October 2012 Complete Response Letter for TOBI Podhaler (the provisional US trade name) in October 2012 and anticipates an FDA action in the middle of 2013. An FDA Advisory Committee previously voted 13 to 1 that there was adequate evidence of efficacy and safety to support its use in the proposed indication.

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Zortress/Certican (\$210 million, +20% cc), a transplantation medicine available in more than 90 countries to prevent organ rejection in adult heart and kidney transplant patients, continued to generate robust growth. It is also approved to prevent organ rejection for liver transplant patients in the European Union (as of October 2012), Argentina, Chile and Philippines. Everolimus, the active ingredient in Zortress/Certican, is marketed for other indications under the trade names Afinitor/Votubia. Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

*Extavia* (\$159 million, +9% cc), the Novartis-branded version of Betaferon®/Betaseron® (interferon beta-1b) for relapsing forms of MS, continued to grow in key markets. *Extavia* is available in more than 35 countries, including the United States.

Arcapta Neohaler/Onbrez Breezhaler (\$134 million, +39% cc) continued to grow strongly worldwide as a once-daily long-acting beta<sub>2</sub>-agonist (LABA) for the maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). Indacaterol, the active ingredient in Arcapta Neohaler/Onbrez Breezhaler, is now approved in more than 90 countries.

*Ilaris* (\$72 million, +56% cc) showed strong growth as a treatment for adults and children suffering from cryopyrin-associated periodic syndrome (CAPS), a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life threatening amyloidosis. *Ilaris* is approved for the treatment of CAPS in over 60 countries.

In January 2013, the CHMP of the EMA has adopted a positive opinion of *Ilaris* (canakinumab) for the treatment of patients whose acute gouty arthritis cannot be managed with standard of care. Approval by the European Commission is expected in the first half of 2013.

Jakavi (\$30 million) sales grew as an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases and was approved in the European Union and Canada in the second half of 2012 for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. Jakavi is available in 31 countries with additional worldwide regulatory filings underway. Incyte holds the rights for Jakavi in the United States where it is sold as Jakavi®.

### Alcon

Net sales rose 3% (+5% cc) to \$10.2 billion, driven by sales growth in Surgical (+5%, +8% cc), Ophthalmic Pharmaceuticals (+2%, +5% cc), and Vision Care (+1%, +4% cc) compared to the prior year.

Surgical sales growth was led by robust sales of Cataract, Vitreoretinal and Refractive equipment, advanced technology IOLs and procedural growth in Emerging Growth Markets. Ophthalmic Pharmaceuticals sales benefited from growth of the *Systane* (Dry Eye), *Nevanac* (Inflammation) and *Durezol* (Inflammation) brands, as well as strong growth in combination glaucoma brands *DuoTrav* and *Azarga*. The Ophthalmic Pharmaceuticals performance was offset by sales of *Travatan* in the United States with the generic entry of latanoprost into the glaucoma category. Vision Care maintained its solid sales performance with growth of *Air Optix*, a strong launch uptake of *Dailies Total1* lenses in Europe, and modest growth in the lens care solution business.

Alcon division net sales by product category:

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in \$	Constant currencies change
	\$ m	\$ m	%	%
Surgical				
Cataract products	2,932	2,858	3	6
of which cataract IOLs	1,281	1,276	0	4
Vitreoretinal products	578	529	9	12
Refractive/other	242	200	21	24
Total	3,752	3,587	5	8
Ophthalmic Pharmaceuticals				
Glaucoma	1,259	1,287	(2)	1
Allergy/otic/nasal	901	884	2	3
Infection/inflammation	1,011	967	5	8
Dry eye/other	848	810	5	8
Total	4,019	3,948	2	5
Vision Care				
Contact lenses	1,732	1,701	2	5
Solutions/other	722	722	0	2
Total	2,454	2,423	1	4
Total net sales	10,225	9,958	3	5

### Alcon Division Franchise Highlights

Net sales growth data below refer to 2012 worldwide performance.

### Surgical

In 2012, global Surgical net sales were \$3.8 billion, up 5% (+8% cc) over the previous year. Advanced technology IOLs showed continued strong growth of 13% (+16% cc), led by *AcrySof IQ Toric*. The launch of the *AcrySof IQ ReSTOR* +2.5D *Multifocal IOL* and *AcrySof IQ ReSTOR* +2.5D *Multifocal Toric IOL* in Europe also contributed to growth.

Global sales of *LenSx* femtosecond cataract refractive lasers grew 234% (cc), continued global launches contributing to strong *LenSx* uptake. *LenSx* lasers have now been installed or shipped to more than 40 markets and more than 1,000 surgeons have been trained to use this innovative technology. In addition, the *LenSx SoftFit* Patient Interface, Alcon's latest *LenSx* laser platform, was launched in the United States for use during cataract surgery.

Surgical also experienced growth in the Vitreoretinal category, driven by sales of *Constellation* equipment, which grew 28% (cc) in markets outside the United States. The Refractive/Other segment also grew, driven by *Wavelight FS200* and *EX500* product launches, offering faster treatment times during refractive surgery.

### Ophthalmic Pharmaceuticals

Global net sales of Ophthalmic Pharmaceuticals products increased by 2% (+5% cc) in 2012, driven by non-US glaucoma product sales, inflammation products *Durezol* and *Nevanac*, and the *Systane* dry eye portfolio. *Travatan/DuoTrav* solution sales in glaucoma grew by 12% (cc) in markets outside the United

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States, offset by the impact of generic competition in the United States. Infection/Inflammation product sales grew 10% (cc), led by strong growth of the *Durezol* emulsion and *Nevanac* ophthalmic suspension. *Systane Ultra* and *Systane Balance* were key growth drivers in the Dry Eye segment in Europe, Latin America, the Caribbean, Canada and Asia, with total product portfolio growth of 10% (cc).

Further strengthening growth prospects for Ophthalmic Pharmaceuticals, Alcon received FDA approval for *Durezol* to treat uveitis in 2012. Originally indicated for use as an anti-inflammatory post-surgery, this additional indication will treat inflammation in the uvea near the middle of the eye. *Nevanac* received EU approval for the indication of post-surgical macular edema to treat the inflammatory response in the retina following cataract surgery. In addition, FDA approval was received for *Nepafenac* ophthalmic suspension 0.3% for the treatment of pain and inflammation associated with cataract surgery. Alcon expanded its pharmaceutical offering by entering into a strategic licensing agreement with ThromboGenics to commercialize *Jetrea* (ocriplasmin) outside the United States. Ocriplasmin, which received a positive CHMP opinion in January 2013, may become the first pharmaceutical treatment for vitreomacular traction and macular hole in Europe. In October 2012, *Jetrea* was approved by the FDA.

#### Vision Care

The Vision Care business continued to grow, with global net sales up 1% (+4% cc, with 5% cc growth in contact lenses and 2% cc growth in lens care products) versus prior year. This growth was driven by the United States and Japan, as well as the continued strong performance of the *Air Optix* portfolio, which leads the marketplace in the multifocal segment and achieved 19% (cc) growth in 2012. Alcon also saw strong *Dailies* growth in the United States, up 14% (cc) over the previous year. *Dailies Total1*, the industry's first and only water gradient contact lens, was launched in Germany, Austria, Italy and France, gaining new users and market share in the silicone hydrogel daily disposable category, and was also approved in the United States and Japan. In lens care, Alcon achieved 10% (cc) growth of the *Clear Care* disinfecting solution.

#### Sandoz.

Sandoz net sales decreased by 8% (-4% cc) in 2012 to \$8.7 billion as a result of declines in the United States retail generics and biosimilars (-17% cc) and Germany (-7% cc), partly offset by double-digit sales growth in biosimilars (+36%), the rest of Western Europe (+10% cc) and Asia (+17% cc). Total sales volume decreased 1 percentage point and price erosion was 5 percentage points primarily due to increased competition on United States sales of enoxaparin (\$451 million in 2012 compared to \$1.0 billion in 2011). Fougera contributed 2 additional percentage points of growth from the inclusion of approximately five months of sales in 2012.

#### Vaccines and Diagnostics

Net sales were \$1.9 billion (-7%, -4% cc) in 2012 compared to \$2.0 billion in 2011. 2011 was impacted by the release of bulk pediatric shipments that had been delayed from the fourth quarter of 2010 and a one-time pre-pandemic sale.

The growth of our Meningococcal franchise was underpinned by *Menveo*, which continues to gain market share both in the United States and in the rest of the world, with sales of over \$164 million (+18% cc) in 2012.

# Consumer Health

Consumer Health net sales declined 19% (-16% cc) mainly due to the impact of the suspension of production at the United States manufacturing site in Lincoln, Nebraska, where operations were suspended at the end of 2011 for quality upgrades and improvements.

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OTC's net sales declined sharply versus the previous year primarily due to Lincoln. Also contributing to the sales decline was a weak cough-and-cold season in early 2012, as well as continued economic deterioration and government austerity measures in several European markets. Despite weak economic conditions, OTC gained market share in most European countries and is growing significantly ahead of the market in key Emerging Growth Markets, notably Russia and China. Increased advertising and promotion investments in growth brands like *Voltaren* and *Otrivin*, the launch of line extensions, and the improvement of commercial execution are the key drivers for these market share gains.

Animal Health reported a net sales decline as a result of limited sales of companion animal products manufactured at Lincoln. Excluding the Lincoln brands, Animal Health maintained strong single-digit growth. The United States continued to show strong momentum, delivering double-digit sales growth excluding the Lincoln brands, mainly driven by *Denagard*, *Atopica* and *Capstar*. Emerging Growth Markets posted high single-digit sales growth with particularly strong performances in China, India, Russia and Brazil.

#### **Operating Income by Segments**

	Year ended Dec 31, 2012 \$ m	% of net sales	Year ended Dec 31, 2011	% of net sales	Change in \$	Change in constant currencies
Pharmaceuticals	9,598	29.9	8,296	25.5	16	19
Alcon	1,465	14.3	1,472	14.8	0	6
Sandoz	1,091	12.5	1,422	15.0	(23)	(24)
Vaccines and Diagnostics	(250)	(13.5)	(249)	(12.5)	0	13
Consumer Health	48	1.3	727	15.7	(93)	(89)
Corporate income & expenses,						
net	(441)		(670)		(34)	(31)
Operating income	11,511	20.3	10,998	18.8	5	8

# **Core Operating Income by Segments**

	Year ended Dec 31, 2012 \$ m	% of net sales	Year ended Dec 31, 2011 \$ m	% of net sales	Change in \$	Change in constant currencies %
Pharmaceuticals	10,213	31.8	10,040	30.9	2	5
Alcon	3,698	36.2	3,492	35.1	6	9
Sandoz	1,503	17.3	1,921	20.3	(22)	(21)
Vaccines and Diagnostics	(75)	(4.0)	135	6.8	nm	nm
Consumer Health	159	4.3	873	18.9	(82)	(78)
Corporate income & expenses,						
net	(338)		(552)		(39)	(35)
Core operating income	15,160	26.7	15,909	27.2	(5)	(2)

nm = not meaningful

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### **Pharmaceuticals**

Pharmaceuticals reported an operating income of \$9.6 billion (+16%, +19% cc). The operating income margin increased by 4.3 percentage points (cc) with a positive currency impact of 0.1 percentage points resulting in an operating income margin of 29.9% of net sales.

Adjustments to arrive at core operating income amounted to \$615 million, consisting of \$322 million for the amortization of intangible assets, \$238 million of impairments and \$55 million of other exceptional charges. The prior year adjustments amounted to \$1.7 billion, principally related to impairments and other charges of \$903 million for *TekturnalRasilez* and restructuring charges of \$420 million offset by a \$334 million gain due to the divestment of Elidel®.

Core operating income was \$10.2 billion (+2%, +5% cc). Constant currency core operating income margin improved by 0.7 percentage points due to continuing productivity efforts. Currency movements had a positive impact of 0.2 percentage points resulting in a core operating income margin of 31.8% of net sales. The underlying gross margin decreased by 1.1 percentage points (cc), mainly driven by royalties and product mix, while R&D expenses improved margin by 0.3 percentage points (cc). As a percentage of net sales, Marketing & Sales and General & Administration expenses improved operating income margin by 0.8 percentage points (cc). Other Income and Expense, net also improved margin by 0.7 percentage points (cc).

As shown below, Pharmaceuticals expensed \$6.9 billion (on a core basis \$6.7 billion) in research and development in 2012. This represented 21.5% (on a core basis 20.8%) of Pharmaceuticals' total net sales. Pharmaceuticals currently has 138 projects in clinical development.

Research and Exploratory Development expenditure was \$2.6 billion in 2012, practically unchanged from the 2011 amount of \$2.7 billion. Confirmatory Development expenditures in 2012 decreased by 5% to \$4.3 billion as compared against 2011. This included \$0.1 billion (2011: \$0.3 billion) in impairments of intangible assets. On a core basis, Confirmatory Development expenditure remained unchanged at \$4.2 billion in 2012 and represented 13.0% of net sales as in the prior year.

### Pharmaceuticals Research and Development Expenditure

	2012 \$ m	Core R&D 2012 <sup>(1)</sup> \$ m	2011 \$ m	Core R&D 2011 <sup>(1)</sup> \$ m
Research and Exploratory Development	2,584	2,530	2,676	2,625
Confirmatory Development	4,334	4,167	4,556	4,235
Total	6,918	6,697	7,232	6,860

Core excludes impairments, amortization and other exceptional items.

### Alcon

(1)

Operating income of \$1.5 billion (0%, +6% cc) included amortization of intangible assets of \$1.9 billion and integration costs of \$264 million, whereas 2011 included an exceptional income of \$268 million.

Adjustments to arrive at core operating income amounted to \$2.2 billion (2011: \$2.0 billion), mainly driven by the amortization of intangible assets of \$1.9 billion (2011: \$1.9 billion).

Alcon increased core operating income to \$3.7 billion (+6%, +9% cc), delivering strong operating leverage through productivity gains and the realization of merger-related cost synergies (2012: \$297 million), while continuing to invest in Emerging Growth Markets and R&D. Core operating margin in constant currencies increased by 1.1 percentage points to 36.2% of net sales. Gross margin in

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constant currencies improved 0.4 percentage points to 74.6% of net sales driven by procurement savings and productivity initiatives. Marketing & Sales expenses, which represented 24.1% of net sales, improved by 1.4 percentage points (cc) due to synergies. General & Administration expenses improved 0.1 percentage points (cc) to 4.9% of net sales. Investments in R&D represented 9.1% of net sales, decreasing 0.4 percentage points (cc) from the prior year.

#### Sandoz

Operating income at Sandoz was \$1.1 billion (-23%, -24% cc). The operating income margin fell by 3.1 percentage points in constant currencies, with a positive currency impact of 0.6 percentage points resulting in an operating income margin of 12.5% of net sales, as a result of enoxaparin-driven price erosion and continued investments into quality assurance and manufacturing as well as into the development of future biosimilar and respiratory products.

Adjustments to arrive at core operating income amounted to \$412 million (2011: \$499 million). These consist principally of amortization of intangible assets of \$364 million (2011: \$383 million) and costs related to the Fougera acquisition of \$62 million. These were partly offset by a reduction of contingent consideration of \$59 million related to a business combination (2011: \$106 million) and lower legal settlement costs compared to prior year of \$204 million.

Core operating income decreased by 22% (-21% cc) to \$1.5 billion. The addition of the Fougera business contributed 1.0 percentage points (cc) to core operating income. Core operating income margin in constant currencies decreased by 3.7 percentage points, partly offset by a positive currency impact of 0.7 percentage points, resulting in a core operating income margin of 17.3% of net sales. Gross margin decreased by 0.9 percentage points (cc), driven primarily by continued investments in quality assurance and manufacturing. R&D expenses (-1.1 percentage points cc) increased as a result of development investments in biosimilars and respiratory products. As a percentage of net sales, Marketing & Sales expenses increased by 1.5 percentage points (cc) as a consequence of investments into growing businesses in biosimilars, Western Europe outside of Germany and Emerging Growth Markets. R&D expenses increased by 1.1 percentage points (cc) as a result of our investments into our biosimilars and respiratory pipeline and General & Administration expenses increased by 0.2 percentage points (cc). Other Income and Expense, net was unchanged compared to 2011.

# Vaccines and Diagnostics

Reported operating loss was \$250 million (2011: \$249 million loss) as a result of lower sales and the manufacturing ramp-up for upcoming launches of *Bexsero* and *Flucelvax*. 2012 included a licensing settlement benefit of \$56 million, while 2011 included an impairment of \$135 million related to a financial asset.

Core operating loss in 2012 was \$75 million compared to a core operating income of \$135 million in 2011.

### Consumer Health

Consumer Health reported an operating income of \$48 million versus a prior-year income of \$727 million largely due to the impact of the suspension of production and quality upgrade investments at Lincoln, as well as higher income in 2011 from the divestment of OTC non-core brands.

The operating income margin declined 14.4 percentage points to 1.3% of net sales, including a negative currency impact of 0.6 percentage points. Core operating income declined 82% (-78% cc) to \$159 million and core operating income margin declined 14.6 percentage points to 4.3% of net sales.

Gross margin decreased 9.4 percentage points (cc) mainly due to disruptions in supply, idle capacity charges at Lincoln as well as one-time quality upgrade investments at the manufacturing facility. As a percentage of net sales, Marketing & Sales expenses increased 2.4 percentage points (cc), R&D expenses

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increased 1.4 percentage points (cc) and General & Administration expenses increased 0.9 percentage points (cc) largely as a result of lower sales that more than offset the positive impact from cost savings programs. During 2012, both Consumer Health businesses continued to increase overall R&D spending to support their future pipelines and also increased Marketing & Sales spend into products and markets that were not affected by the supply shortage. Other Income and Expense, net increased by 0.1 percentage points (cc).

### Corporate Income and Expense, Net

Corporate income and expense, which includes the cost of Group management and central services, amounted to a \$441 million net expense, compared to \$670 million in 2011, principally due to reductions in environmental, restructuring and other provisions and an exceptional gain of \$51 million from the sale of financial assets. Taking into account 2012 core adjustments of \$103 million, core corporate income and expense decreased to a net expense of \$338 million (2011: \$552 million).

## **Non-Operating Income and Expense**

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Operating income	11,511	10,998	5	8
Income from associated companies	552	528	5	5
Interest expense	(724)	(751)	(4)	(1)
Other financial income and expense	(96)	(2)	nm	nm
Income before taxes	11,243	10,773	4	7
Taxes	(1,625)	(1,528)	6	8
Group net income	9,618	9,245	4	7
Attributable to:				
Shareholders of Novartis AG	9,505	9,113	4	8
Non-controlling interests	113	132	(14)	(14)
Basic EPS (\$)	3.93	3.83	3	6

nm=

not meaningful

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# **Core Non-Operating Income and Expense**

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in \$	Change in constant currencies %
	\$ m	\$ m	%	%
Core operating income	15,160	15,909	(5)	(2)
Income from associated companies	755	779	(3)	(3)
Interest expense	(724)	(751)	(4)	(1)
Other financial income and expense	(96)	(2)	nm	nm
Core income before taxes	15,095	15,935	(5)	(3)
Taxes	(2,284)	(2,445)	(7)	(5)
Core net income	12,811	13,490	(5)	(3)
Attributable to:				
Shareholders of Novartis AG	12,698	13,273	(4)	(2)
Non-controlling interests	113	217	(48)	(48)
Core basic EPS (\$)	5.25	5.57	(6)	(3)

nm = not meaningful

#### **Income From Associated Companies**

The income from associated companies increased from \$528 million in 2011 to \$552 million in 2012.

The following is a summary of the individual components included in the income from associated companies:

	2012	2011
	\$ m	\$ m
Novartis share of Roche's estimated current-year consolidated net income	691	661
Amortization of additional intangible assets recognized by Novartis on initial accounting for the equity interest	(153)	(162)
Net income effect from Roche	538	499
Net income from other associated companies	14	29
Income from associated companies	552	528

The Group's 33.3% interest in Roche's voting shares, which represents a 6.4% interest in Roche's total equity, generated income of \$538 million in 2012, up from \$499 million in 2011. The 2012 contribution reflects an estimated \$741 million share of Roche's net income in 2012. This contribution, however, was reduced by an exceptional charge of \$50 million taken in 2012 as part of Roche's restructuring charges and \$153 million for the amortization of intangible assets arising from the allocation of the purchase price paid by Novartis for this investment to Roche's intangible assets. A survey of analyst estimates is used to estimate the Group's share of net income in Roche. Any differences between these estimates and actual results will be adjusted in the 2013 consolidated financial statements.

Adjusting for the exceptional items in both years, core income from associated companies decreased 3% from \$779 million to \$755 million.

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# Interest Expense and other Financial Income/Expense

The interest expense decreased to \$724 million in 2012 from \$751 million in 2011 as a result of lower average gross financial debt compared to the prior year. Other financial income and expense amounted to a net expense of \$96 million compared to a net expense of \$2 million in 2011, mainly as a result of currency losses.

#### Taxes

Tax expenses in 2012 were \$1.6 billion, an increase of 6% (8% cc) from 2011. The tax rate (taxes as a percentage of income before taxes) increased slightly to 14.5% in 2012 from 14.2% in 2011. The core tax rate (taxes as percentage of core income before taxes) decreased to 15.1% in 2012 from 15.3% in 2011.

For further information on the main elements contributing to the difference, see " Core Results" and "Item 18. Financial Statements note 6".

### **2011 Compared to 2010**

### **Key Figures**

	Year ended Dec 31, 2011 \$ m	Year ended Dec 31, 2010 \$ m	Change in \$	Change in constant currencies %
Net sales	58,566	50,624	16	12
Other revenues	809	937	(14)	(15)
Cost of goods sold	(18,983)	(14,488)	31	25
Gross profit	40,392	37,073	9	7
Marketing & Sales	(15,079)	(13,316)	13	9
Research & Development	(9,583)	(9,070)	6	(2)
General & Administration	(2,970)	(2,481)	20	12
Other income	1,354	1,234	10	(4)
Other expense	(3,116)	(1,914)	63	48
Operating income	10,998	11,526	(5)	1
Income from associated companies	528	804	(34)	(34)
Interest expense	(751)	(692)	9	5
Other financial income and expense	(2)	64	(103)	(140)
Income before taxes	10,773	11,702	(8)	(2)
Taxes	(1,528)	(1,733)	(12)	(6)
	( ))	( ),	( )	(-)
Net income	9,245	9,969	(7)	(2)
1 (ct meome	), <u>2</u> 40	,,,,,,	(7)	(2)
Attributable to:				
Shareholders of Novartis AG	9,113	9,794	(7)	(1)
Non-controlling interests	132	175	(25)	(25)
Basic earnings per share	3.83	4.28	(11)	(5)
basic carnings per snare	3.03	126	(11)	(3)
		120		

#### **Core Key Figures**

	Year ended Dec 31, 2011	Year ended Dec 31, 2010	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Core gross profit	43,839	38,517	14	11
Marketing & Sales	(15,077)	(13,315)	13	9
Research & Development	(9,239)	(8,080)	14	7
General & Administration	(2,957)	(2,477)	19	11
Other income	443	485	(9)	(43)
Other expense	(1,100)	(1,124)	(2)	(19)
Core operating income	15,909	14,006	14	16
Core net income	13,490	12,029	12	15
Core basic earnings per share	5.57	5.15	8	11

The Group's core results exclude the amortization of intangible assets, impairment charges, expenses relating to the integration of acquisitions as well as other items that are, or are expected to accumulate within the year to be, over a \$25 million threshold that management deems exceptional.

#### **Overview Results Operations**

Net sales rose 16% (+12% cc) to \$58.6 billion in 2011, with a positive currency impact of 4% arising from the weakness of the US dollar against most major currencies during much of 2011. Sales of recently launched products (products launched since 2007, except Sandoz products launched in last 24 months) grew 38% (in \$, excluding the A(H1N1) pandemic flu vaccine including Alcon on a pro forma basis for 2010) over 2010 to \$14.4 billion. These products contributed 25% of Group net sales, up from 19% in 2010.

Operating income was down 5% (+1% cc) to \$11.0 billion. The weakness of the US dollar, combined with the strong Swiss franc, resulted in a negative currency impact of 6 percentage points. Cost of goods sold rose by 31% (25% cc) to \$19.0 billion in 2011, increasing by 3.8 percentage points to 32.4% of net sales. This led to a reduction in the gross margin by 4.2% to 69.0%. Marketing & Sales rose 13% (9% cc) to \$15.1 billion, improving 0.6 percentage points to 25.7% of net sales, as productivity improvements and changes in the portfolio mix were partly offset by investments in new launch products. Research & Development expenses increased by 6% (-2% cc) in 2011 to \$9.6 billion. This included \$341 million in impairments of intangible assets. General & Administration expenses increased 20% (12% cc) to \$3.0 billion. Other income was up 10% (-4% cc) to \$1.4 billion and largely consists of gains from product disposals, legal settlements and certain items of net periodic pension cost. Other expense was up 63% (48% cc) to \$3.1 billion and includes impairment of financial assets as well as property plant and equipment, litigation settlement costs, restructuring and related charges and acquisition related integration expenses.

Core operating income, which excludes exceptional items and amortization of intangible assets, was up 14% (16% cc) to \$15.9 billion. Core operating income margin in constant currencies increased by 1.1 percentage points. However, this improvement was more than offset by a negative currency impact of 1.6 percentage points, resulting in a net decrease in core operating income margin of 0.5 percentage points to 27.2% of net sales. Total net exceptional income and expense adjusted in core results in the various line items in 2011 amounted to \$1.9 billion expense compared to \$1.3 billion in the prior year. It comprised charges of \$2.9 billion (2010: \$2.1 billion) partly offset by exceptional income of \$1.0 billion (2010: \$732 million). Exceptional charges included: *Tekturna/Rasilez* (\$903 million); \$348 million related to the discontinuation of the PRT128 (elinogrel), SMC021 (oral calcitonin), AGO178 (agomelatine), and PTK796 (omadacycline) development programs; a charge of \$115 million related to the temporary suspension of production at one of our US Consumer Health sites; other intangible asset impairment

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charges of \$71 million principally relating to development projects; financial asset impairment charges of \$192 million; integration charges of \$250 million (mainly for Alcon); and restructuring and related costs of \$492 million. Exceptional income includes divestment proceeds (\$480 million) and a \$106 million reduction of a contingent consideration obligation in Sandoz. In 2011, amortization of intangible assets amounted to \$3.0 billion compared to \$1.1 billion in 2010 as a result of a full year of incorporating Alcon.

Net income decreased 7% (-2% cc) to \$9.2 billion, more than the decline in operating income as a result of lower associated company income, higher financing costs following the Alcon acquisition, partly offset by a lower tax rate (14.2% compared to 14.8%). EPS declined 11% (-5% cc), more than the decline in net income, mainly as a result of the increase in issued shares following the Alcon merger, partially offset by a lower impact from non-controlling interests.

Core net income grew 12% (+15% cc) to \$13.5 billion broadly in line with core operating income. Core EPS was up by 8% (+11% cc): a lower rate than net income as a result of a higher number of outstanding shares in 2011.

The average number of shares outstanding in 2011 rose 4% to 2,382 million from 2,286 million in the year ago, while a total of 2,407 million shares were outstanding at December 31, 2011.

Free cash flow reached \$12.5 billion (2010: \$12.3 billion), an increase of 1% over the previous year. Free cash flow in 2010 included substantial cash flows from sales of A(H1N1) amounting to \$1.8 billion.

### **Net Sales by Segment**

	Year ended Dec 31, 2011	Year ended Dec 31, 2010 <sup>(1)</sup>	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Pharmaceuticals	32,508	30,306	7	4
Alcon	9,958	4,446	124	118
Sandoz	9,473	8,592	10	7
Vaccines and Diagnostics	1,996	2,918	(32)	(34)
Consumer Health	4,631	4,362	6	3
Net sales	58,566	50,624	16	12

Restated to reflect new segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

Pharmaceuticals net sales grew 7% (+4% cc) to \$32.5 billion, and Alcon net sales of \$10.0 billion rose 10% (+7% cc) on a pro forma basis. Sandoz net sales also grew 10% (+7% cc) to \$9.5 billion. Vaccines and Diagnostics net sales were down 32% (-34% cc) to \$2.0 billion, mainly due to \$1.3 billion of A(H1N1) pandemic flu vaccine sales in 2010. Net sales of the two Consumer Health businesses together grew 6% (+3% cc) to \$4.6 billion.

### **Pharmaceuticals**

Net sales expanded 7% (+4% cc) to \$32.5 billion in 2011 driven by 9 percentage points of increased volume, partly offset by a negative pricing impact of 1 percentage point and the combined impact of generic entries and product divestments of an additional 4 percentage points. Recently launched products (products launched since 2007) contributed \$9.2 billion of net sales, growing 35% in constant currencies over the previous year. These products now represent 28% of division sales compared to 22% in 2010.

Europe remained the largest region (\$11.6 billion, +2% cc) for Pharmaceuticals, particularly benefiting from recently launched products, which generated 35% of net sales, more than offsetting health care cost-containment measures and generic erosion. The US (\$10.0 billion, 0% cc) contributed 31% of

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net sales for the division. Japan's performance (\$3.9 billion, +7% cc) improved versus the prior year due to new launches. Latin America and Canada (\$3.0 billion, +10% cc) achieved strong growth rates. The top six emerging markets (\$3.2 billion, +7% cc) were led by double-digit growth from China and India.

### TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2011

			Net sales	Change in	Net sales	Change in		(	Change in
_	Business			constant			Total	Change c	
Brands	Franchise	Indication		currencies					rrencies
			\$ m	%	\$ m	%	\$ m	%	%
Diovan/Co Diovan	Primary care	Hypertension	2,333	(7)	3,332	(11)	5,665	(6)	(9)
Gleevec/Glivec	Oncology	Chronic myeloid leukemia	1 450	14	3,200	2	4.650	9	5
Lucentis	Ophthalmics	Age-related macular	1,459	14	3,200	2	4,659	9	3
Lucius	Ophthanines	degeneration			2,050	26	2.050	34	26
Zometa	Oncology	Cancer			2,000	20	2,000		20
	<i></i>	complications	642	(11)	845	0	1,487	(2)	(5)
Sandostatin	Oncology	Acromegaly	574	12	869	7	1,443	12	9
Exforge	Primary care	Hypertension	325	14	884	36	1,209	34	30
Exelon/Exelon Patch	Neuroscience	Alzheimer's disease	375	(1)	692	7	1,067	6	4
Femara	Oncology	Breast cancer	219	(66)	692	(11)	911	(34)	(37)
Neoral/Sandimmun	Integrated	Transplantation							
	Hospital Care		71	( - /	832	(1)	903	4	(2)
Exjade	Oncology	Iron chelator	259	(2)	591	13	850	12	8
Voltaren (excl. OTC)	Additional	Inflammation/pain							
	products		4	0	790	1	794	0	2
Tasigna	Oncology	Chronic myeloid leukemia	255	90	461	66	716	79	74
Galvus	Primary care	Diabetes			677	66	677	73	66
Comtan/Stalevo	Neuroscience	Parkinson's disease	214	(7)	400	3	614	2	(1)
Reclast/Aclasta	Established	Osteoporosis							
	medicines		386	` /	227	18	613	6	5
Tekturna/Rasilez	Primary care	Hypertension	216	4	341	41	557	27	24
Ritalin/Focalin	Additional	Attention							
	products	Deficit/Hyperactive Disorder	398	17	152	14	550	19	17
Myfortic	Integrated	Transplantation	398	1 /	132	14	330	19	1 /
тујони	Hospital Care	Transplantation	200	23	318	11	518	17	15
Gilenya	Neuroscience	Relapsing Multiple	200		510		210		
<b>V</b>		Sclerosis	383	nm	111	nm	494	nm	nm
Xolair	Critical Care	Asthma	15	(38)	463	35	478	30	29
Top 20 products total			8,328	2	17,927	8	26,255	9	6
Rest of portfolio			1,645		4,608	(1)	6,253	0	(4)
•			•	. /	•	. /	•		. /
Total Division sales			9,973	0	22,535	6	32,508	7	4
			. ,		,	_	- ,		

nm = not meaningful

# Pharmaceuticals Division Product Highlights Selected Leading Products

Net sales growth data below refer to 2011 worldwide performance. Growth rates are not provided for some recently launched products since they are not meaningful.

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#### Cardiovascular and Metabolism

*Diovan* Group (-6% to \$5.7 billion, -9% cc) worldwide sales declined due to loss of exclusivity in the EU. *Diovan* Group remains the top-selling anti-hypertensive medication worldwide, with 13.27% of the global hypertension market.

Exforge Group (+34% to \$1.2 billion, +30% cc), showed strong worldwide growth fueled by continued prescription demand in the EU, US and other key regions, as well as ongoing Exforge HCT launches in Europe, Asia and Latin America. Exforge, a single-pill combination of Diovan and the calcium channel blocker amlodipine, has delivered excellent growth globally and is now available in over 80 countries. Exforge HCT, Exforge with a diuretic (hydrochlorothiazide) in a single pill, is now available for patients in over 40 countries with additional launches expected in 2012.

Tekturna/Rasilez (+27% to \$557 million, +24% cc), the first in a class of medicines known as direct renin inhibitors to treat high blood pressure, has been growing consistently since its launch in 2007. However, in late December, following the seventh interim review of data from the ALTITUDE study with Tekturna/Rasilez, Novartis announced that the trial was halted on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the study. The DMC concluded that patients were unlikely to benefit from treatment on top of standard anti-hypertensive medicines, and identified higher adverse events in patients receiving Tekturna/Rasilez in addition to standard of care as part of the trial. Novartis has written to healthcare professionals worldwide recommending that hypertensive patients with diabetes should not be treated with Tekturna/Rasilez, or combination products containing aliskiren (the active ingredient in Tekturna/Rasilez), if they are also receiving an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB). As an additional precautionary measure, Novartis has ceased promotion of Tekturna/Rasilez-based products for use in combination with an ACE inhibitor or ARB. In 2011, single-pill combinations Rasilamlo, a dual combination of aliskiren and amlodipine, and Rasitrio, a triple combination of aliskiren, amlodipine and hydrochlorothiazide, were approved in the EU. These single-pill combinations were also launched in the US in 2011 under the brand names Tekamlo and Amturnide, respectively.

Galvus/Eucreas (+73% to \$677 million, +66% cc), which includes oral treatments with vildagliptin for type 2 diabetes, has shown strong growth in Japan and many European, Latin American and Asian Pacific markets since launch in 2007. The single-pill combination Eucreas/GalvusMet (vildagliptin and metformin) accounted for the majority of sales, with the expanded use of Galvus in elderly patients over 75 years old in the EU also fueling growth in 2011. Additional EU approvals for use in moderate or severe renally impaired type 2 diabetes patients are expected to drive growth in 2012. Vildagliptin is now approved in more than 90 countries with an additional launch expected in China in 2012.

#### Oncology

Gleevec/Glivec (+9% to \$4.7 billion, +5% cc), a targeted therapy for some forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST), maintained solid growth based on its leadership position in treating these cancers. New clinical data showing significant survival benefits for adult patients with resected KIT+ GIST who received adjuvant (post-surgery) treatment with Gleevec/Glivec (imatinib) for three years compared to one year following surgery served as the basis for worldwide regulatory filings to update the label. Gleevec/Glivec was approved in 2008 for use in certain adjuvant (post-surgery) KIT+ GIST patients and is now approved in more than 60 countries for this indication.

Tasigna (+79% to \$716 million, +74% cc), has shown rapid growth as a next-generation targeted therapy for newly diagnosed Ph+ CML patients following approvals in more than 50 markets globally including the US, EU, Japan and Switzerland, with additional submissions pending worldwide. Tasigna market share continues to rise in Ph+ CML in the second-line indication with approvals in over 95 countries.

Zometa (-2% to \$1.5 billion, -5% cc) is an intravenous bisphosphonate therapy for patients with certain types of cancer that has spread to the bones. Zoledronic acid, the active ingredient in *Zometa* (4 mg), is also available under the trade names *Reclast/Aclasta* (5 mg) for use in non-oncology indications with different dosing. *Zometa* is facing new competition from denosumab, a product of Amgen.

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Femara (-34% to \$911 million, -37% cc), a treatment for early stage and advanced breast cancer in postmenopausal women, experienced a decline in sales due to multiple generic entries in the US, Europe and other key markets.

Sandostatin (+12% to \$1.4 billion, +9% cc) benefited from the increasing use of Sandostatin LAR in treating symptoms of patients with neuroendocrine tumors as well as approvals in 25 countries for the delay of tumor progression in patients with midgut carcinoid tumors. It is currently under review in more than 20 additional countries for this indication.

*Exjade* (+12% to \$850 million, +8% cc) continued to expand with strong growth based on new patients and expanded access led by Asia and Europe. *Exjade* is currently approved in more than 100 countries as the only once-daily oral therapy for transfusional iron overload. Filings for a potential new indication in the treatment of non-transfusion-dependent thalassemia were submitted in the US and EU.

Afinitor/Votubia (+82% to \$443 million, +77% cc) is an oral inhibitor of the mTOR pathway used across multiple diseases. Afinitor continues to achieve strong growth in key markets as the only approved treatment for patients with advanced renal cell carcinoma following VEGF-targeted therapy. Afinitor expanded its indications with approvals in the US, EU and Japan for the treatment of advanced pancreatic neuroendocrine tumors. Everolimus, the active ingredient in Afinitor, is also approved in the US as Afinitor and in the EU as Votubia for the treatment of subependymal giant cell astryocytomas associated with tuberous sclerosis complex (TSC). A Phase III study of everolimus in patients with non-cancerous kidney tumors, or angiomyolipomas, associated with TSC formed the basis of regulatory filings currently underway for this potential indication. In addition, results of another Phase III study, which showed Afinitor plus exemestane met the primary endpoint of progression-free survival versus exemestane alone in postmenopausal women with HR+/HER2- advanced breast cancer, are supporting worldwide regulatory filings for this potential indication. Everolimus is also available under the trade names Zortress/Certican for use in other non-oncology indications and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

### Neuroscience and Ophtalmics

Lucentis (+34% to \$2.0 billion, +26% cc) is a biotechnology eye therapy now approved in more than 100 countries for the treatment of wet age-related macular degeneration, and in more than 50 countries for the treatment of visual impairment due to diabetic macular edema. Lucentis was approved in June 2011 in Europe for visual impairment due to macular edema secondary to branch- and central-retinal vein occlusion, and is now approved for this indication in more than 50 countries, including China. Genentech/Roche holds the US rights to this medicine.

Exelon/Exelon Patch (+6% to \$1.1 billion, +4% cc) is a therapy for mild to moderate forms of Alzheimer's disease dementia as well as dementia linked with Parkinson's disease. The majority of sales are for Exelon Patch, the novel skin patch launched in 2007 which is now available in more than 80 countries worldwide for Alzheimer's disease dementia, including more than 20 countries where it is also approved for dementia associated with Parkinson's disease.

Extavia (+24% to \$154 million, +19% cc), available in the US and more than 35 other countries for relapsing forms of multiple sclerosis (MS), marked the entry of Novartis into the field of MS. Extavia is the Novartis-branded version of Betaferon®/Betaseron®.

Gilenya (\$494 million) is approved in more than 55 countries and showed continued rapid growth as a once-daily, oral disease-modifying treatment for relapsing remitting and/or relapsing forms of MS in adult patients. Gilenya was approved in the EU in March 2011 as a disease modifying therapy in patients with highly active relapsing-remitting multiple sclerosis (RRMS) despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS. Novartis also received approval for Gilenya in September 2011 in Japan for the prevention of relapse and delay of progression of physical disability in adults with MS. It is licensed from Mitsubishi Tanabe Pharma Corporation.

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#### Respiratory

Xolair (+30% to \$478 million, +29% cc, ex-US), a biotechnology drug approved for severe persistent allergic asthma in Europe and moderate to severe persistent allergic asthma in the US, gained blockbuster status when annual global sales (including US sales recorded by Genentech/Roche) reached \$1 billion in November 2011. Xolair is now approved in 90 countries and has shown strong growth during 2011 in Europe, major Latin American markets and Japan. A Phase III trial is progressing to support registration in China. Launches are continuing across Europe for Xolair Liquid, a new formulation in pre-filled syringes that enables easier administration than the original lyophilized formulation. Phase III studies are also being conducted in an additional potential indication, chronic idiopathic urticaria. Novartis co-promotes Xolair with Genentech/Roche in the US and shares a portion of operating income, but does not record any US sales. Novartis has the sole rights to market Xolair outside the US.

Onbrez Breezhaler/Arcapta Neohaler (\$103 million) has shown strong sales growth since its approval in the EU in November 2009 as a once-daily long-acting beta<sub>2</sub>-agonist (LABA) for the maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). Onbrez Breezhaler (indacaterol, formerly QAB149) is now approved in more than 80 countries, including the US (under the trade name Arcapta Neohaler) as of July 2011 and Japan (under the trade name Onbrez Inhalation Capsules), where it has been co-promoted with Eisai Co. Ltd. since December 2011. Results of two Phase III studies announced in February 2011 showed that patients treated with once-daily Onbrez Breezhaler in conjunction with once-daily tiotropium 18 mcg experienced a significantly greater improvement in lung function than those treated with tiotropium alone, adding to the growing body of evidence supporting the use of Onbrez Breezhaler as an effective treatment for COPD. Sales in Germany were negatively impacted in the fourth quarter of 2011 following a reference pricing review in which the reimbursed price of Onbrez Breezhaler was reduced below that of generic LABAs. Novartis has maintained prices for Onbrez Breezhaler in Germany, since it offers additional benefits over existing LABAs as described in the EU-approved label. An additional co-payment for Onbrez Breezhaler is now required for many patients in Germany.

TOBI Podhaler (\$296 million, including TOBI nebulizer solution) was approved in the EU in July 2011 as a suppressive therapy for chronic Pseudomonas aeruginosa lung infections in patients with cystic fibrosis (CF) aged six years and older. TOBI Podhaler (tobramycin inhalation powder) is a dry powder formulation of the antibiotic tobramycin, developed using novel PulmoSphere technology. This means that instead of using a nebulizer, treatment can be delivered using a more convenient, patient-friendly device that reduces administration time by 72% relative to TOBI (nebulizer solution), with comparable efficacy. TOBI Podhaler is designed to help CF patients, who are often young, to comply with treatment and lead more independent lives.

#### Integrated Hospital Care

Zortress/Certican (+30% to \$187 million, +25% cc) is a transplantation medicine indicated to prevent organ rejection in adult kidney and heart transplant patients. It generated solid growth based on its availability in more than 85 countries, including the US, where it was launched in April 2010 for adult kidney transplantation under the brand name Zortress. This medicine, which has the same active ingredient as Afinitor (everolimus), has demonstrated immunosuppressive efficacy and a well characterized side-effect profile.

*Ilaris* (+85% to \$48 million, +82% cc) is a fully human monoclonal antibody that selectively binds and neutralizes interleukin-1ß (IL-1ß), a proinflammatory cytokine. Since 2009, *Ilaris* has been approved in over 50 countries for the treatment of children and adults suffering from cryopyrin-associated periodic syndrome (CAPS), a group of rare auto-inflammatory disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness and potentially life threatening amyloidosis. Novartis has filed for regulatory approval of *Ilaris* in the EU and the US for the treatment of acute attacks in gouty arthritis based on data from two Phase III registration studies that met their primary endpoints. In August 2011,

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Novartis received a Complete Response letter from the FDA requesting additional information, including clinical data to evaluate the benefit risk profile in refractory gouty arthritis patients. Novartis is currently working with the FDA to determine next steps for ACZ885 in gouty arthritis. Novartis is also pursuing other diseases in which IL-1ß may play a prominent role, such as systemic juvenile idiopathic arthritis, secondary prevention of cardiovascular events and diabetes. Select subsets of patients with these diseases would be eligible for treatment with *Ilaris*, if approved.

Neoral/Sandimmun (+4% to \$903 million, -2% cc), for organ transplantation and autoimmune diseases, has experienced only modestly declining sales despite ongoing generic competition in recent years due to its pharmacokinetic profile, reliability and use in treating a life-threatening condition.

*Myfortic* (+17% to \$518 million, +15% cc), a transplantation medicine, is approved in more than 90 countries for the prevention of acute rejection of kidney allografts and is indicated in combination with cyclosporine and corticosteroids. *Myfortic* was first approved in the US in 2004 and in the EU in 2003.

Other

Reclast/Aclasta (+6% to \$613 million, +5% cc), a once-yearly infusion therapy for osteoporosis, continues to expand on increasing patient access to infusion centers and a broad range of use in patients with various types of this debilitating bone disease. Approvals have been received in over 100 countries for up to six indications, including the treatment of osteoporosis in men and postmenopausal women. Six year data from a pivotal fracture trial reinforced the long-term efficacy and safety profile of Reclast/Aclasta. Zoledronic acid, the active ingredient in Reclast/Aclasta, is also available in a number of countries in a different dosage for use in oncology indications under the trade name Zometa.

Voltaren (0% at \$794 million, +2% cc, excluding OTC sales), a treatment for various inflammation and pain conditions, no longer has patent protection in key markets around the world, but has continued to generate growth in regions such as Latin America, the Middle East, Africa and Asia based on long-term trust in the brand.

*Ritalin/Focalin* (+19% to \$550 million, +17% cc), for treatment of Attention Deficit/Hyperactivity Disorder (ADHD), has benefited from the use of long-acting *Ritalin LA* and *Focalin XR* patent-protected formulations that involve methylphenidate, the active ingredient in *Ritalin* faces generic competition in many countries.

### Alcon

Net sales in 2011 of Alcon increased by 124% to \$10.0 billion on a restated basis. Since however the 2010 base only includes the net sales of Alcon, Inc. from August 25, 2010, as indicated above, a comparison on a 2010 pro forma basis is more meaningful.

Net sales of \$10.0 billion rose 10% (+7% cc) on a pro forma basis, driven by strong global Ophthalmic Pharmaceuticals product growth of 12% (+10% cc), Surgical products growth of 11% (+8% cc), and by the top six emerging markets, which grew 26% (+22% cc) over 2010.

Alcon division pro forma net sales by product category:

	Year ended Dec 31,	Year ended Dec 31,	Change	Constant currencies
	2011	2010	in \$	change
	\$ m	\$ m	%	%
Surgical				
Cataract products	2,858	2,668	7	4
of which Cataract IOLs	1,276	1,207	6	3
Vitreoretinal products	529	424	25	21
Refractive/Other	200	129	55	51
Total	3,587	3,221	11	8
	,	,		
Ophthalmic Pharmaceuticals				
Glaucoma	1,287	1,136	13	10
Allergy/Otic/Nasal	884	813	9	7
Infection/inflammation	967	839	15	14
Dry Eye/Other	810	727	11	10
Total	3,948	3,515	12	10
	,	,		
Vision Care				
Contact lenses	1,701	1,579	8	3
Solutions/Other	713	716		(4)
Total	2,414	2,295	5	1
	,	,		
Total net sales	9,949	9,031	10	7

#### Alcon Division Franchise Highlights

Net sales growth data below refer to 2011 worldwide performance on a pro forma basis.

### Surgical

In 2011, global Surgical net sales were \$3.6 billion, an increase of 11% (+8% cc) over the previous year. Emerging markets grew strongly, while intraocular lens unit sales (IOL) in the US showed slower growth versus 2010. Global sales of advanced technology intraocular lenses rose 16% (+15% cc), mostly due to strong sales of the *AcrySof IQ Toric* and *AcrySof IQ ReSTOR+3.0* intraocular lenses. The successful launch of the *LenSx* femtosecond refractive cataract laser, with over 500 surgeons now trained to use this cutting-edge technology, expands the cataract surgical market opportunities for Alcon. The *Constellation* vitreoretinal surgical system contributed to robust sales growth within the vitreoretinal category. Strong growth in the refractive segment was driven both by sales of equipment and increased market share in the US.

#### Ophthalmic Pharmaceuticals

Global net sales of Ophthalmic Pharmaceuticals products increased 12% (+10% cc) to \$3.9 billion in 2011. Glaucoma product sales rose 13% (+10% cc), with growth driven by non-US combination products *DuoTrav* and *Azarga*, with a combined growth of 41% (+34% cc). Infection/inflammation product sales advanced 15% (+14% cc) led by strong growth of *Nevanac* ophthalmic suspension, as well as solid performance of *Durezol* ophthalmic suspension. Allergy, otic, and nasal products showed solid growth, led by the *PatanollPataday* franchise. Dry eye products *Systane* and *Systane Balance* were the key contributors to growth in that product segment.

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Vision Care

Global net sales of Vision Care products rose 5% (+1% cc) in 2011 to \$2.4 billion. Contact lens growth was driven by the continued strong performance of *Air Optix*, which leads the marketplace in the multifocal segment and achieved 18% (cc) growth over the previous year, and by strong *Dailies* growth in the US. Sales of contact lenses were impacted by the discontinuation of the Specialty contact lens business as well as slower market growth in European countries. Contact lens solutions sales were led by strong growth of the *Clear Care* hydrogen peroxide solution, offset by weakness in the category for multi-purpose product sales.

#### Sandoz

Sandoz achieved strong sales growth in 2011 (+10% to \$9.5 billion, +7% cc) versus prior year driven by significant growth in US retail generics and biosimilars (+22% cc), with sales of over \$1 billion for enoxaparin. Strong performances in Canada (+13% cc), Western Europe (+13% cc), Latin America (+12% cc), Asia (+12% cc) and Central and Eastern Europe (+6% cc) also contributed to growth in 2011. Germany retail generics and biosimilars declined (-13% cc) in a market that is estimated to have contracted 17% in net terms due to the impact of statutory health insurance tenders and new lower reference prices. Biosimilars grew 37% in constant currencies to \$261 million globally. Sales volume expanded 14 percentage points due to new product launches, and Falcon (transferred from Alcon) contributed 2 additional percentage points of growth, more than compensating price erosion of 9 percentage points.

### Vaccines and Diagnostics

Net sales declined 32% to \$2.0 billion in 2011 (-34% cc) compared to \$2.9 billion in 2010. The primary driver of the net sales variance against the prior year was \$1.3 billion of A(H1N1) pandemic flu vaccine sales in 2010 not repeated in 2011.

Excluding the impact of A(H1N1) pandemic flu vaccines sales in 2010, net sales growth was 22% in constant currencies, driven by growth across all strategic franchises, with a particularly strong contribution from our meningococcal disease franchise.

The growth of our meningococcal disease franchise was underpinned by *Menveo*, which continues to gain market share both in the US and worldwide, with net sales of \$142 million in 2011.

#### Consumer Health

Consumer Health (comprising OTC and Animal Health) delivered combined 2011 net sales of \$4.6 billion producing growth of 6% (+3% cc).

OTC delivered low-single-digit growth driven by emerging markets and priority brands. In nine out of the top ten countries for OTC, volume growth outpaced the market. Cough and cold brands, including *Theraflu*, grew strongly behind sustained investment and a stronger season in several markets compared to 2010. *Voltaren* continued to grow through the use of innovative commercial models and a focus on marketing fundamentals, while *Prevacid24HR* benefitted from normalized stock movements compared to 2010. In the US, *Excedrin* sales declined in the fourth quarter due to the temporary suspension of operations and voluntary product recall at OTC's Lincoln, Nebraska, USA site. Expired distribution contracts and divested brands also negatively impacted net sales growth versus the prior year.

Animal Health contributed mid-single-digit net sales growth over the previous year, driven by Germany, Japan, Australia and emerging markets. *CliK* and *Vetrazin* retained their leadership positions in the sheep market in Australia and the UK. *Milbemax* delivered double-digit growth as the number one cat and dog de-wormer in Europe, while *Onsior* gained market share across key European markets and Japan.

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In the swine business, *Denagard* continued to drive strong double-digit growth led by the US. Total US sales were flat despite the negative impact of a competitor entry in the heartworm and flea categories.

### **Operating Income by Segments**

	Year ended Dec 31, 2011	% of net sales	Year ended Dec 31, 2010 <sup>(1)</sup>	% of net sales	Change in \$	Change in constant currencies
	\$ m		\$ m		%	%
Pharmaceuticals	8,296	25.5	8,471	28.0	(2)	4
Alcon	1,472	14.8	796	17.9	85	67
Sandoz	1,422	15.0	1,321	15.4	8	10
Vaccines and Diagnostics	(249)	(12.5)	612	21.0	(141)	(131)
Consumer Health	727	15.7	778	17.8	<b>(7</b> )	4
Corporate income & expenses, net	(670)		(452)			
Operating income	10,998	18.8	11,526	22.8	(5)	1

Restated to reflect new divisional segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

### **Core Operating Income by Segments**

	Year ended Dec 31, 2011 \$ m	% of net sales	Year ended Dec 31, 2010 <sup>(1)</sup> \$ m	% of net sales	Change in \$	Change in constant currencies %
Pharmaceuticals	10,040	30.9	9,586	31.6	5	8
Alcon	3,492	35.1	1,350	30.4	159	146
Sandoz	1,921	20.3	1,742	20.3	10	11
Vaccines and Diagnostics	135	6.8	1,066	36.5	(87)	(85)
Consumer Health	873	18.9	845	19.4	3	12
Corporate income & expenses, net	(552)		(583)			
Core operating income	15,909	27.2	14,006	27.7	14	16

Restated to reflect new divisional segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

## **Pharmaceuticals**

Operating income decreased 2% (+4% cc) in 2011 to \$8.3 billion. Exceptional items including amortization amounted to a net \$1.7 billion expense compared to \$1.1 billion expense in 2010. Exceptional items include *TekturnalRasilez* charges of \$903 million, restructuring charges of \$420 million and other intangible asset impairments of \$302 million (mainly AGO178, PTK796, PRT128 and SMC021). These were partly offset by higher prior-year impairment charges, and divestment income from Elidel® (\$324 million) and from ophthalmic pharmaceutical products related to the Alcon acquisition (\$81 million).

Core operating income in 2011 grew 5% (+8% cc) to \$10.0 billion. In constant currencies, core operating income margin increased by 1.4 percentage points due to continuing productivity efforts. However, this improvement was more than offset by a negative currency impact of 2.1 percentage points, resulting in a net decrease in core operating income margin of 0.7 percentage points to 30.9% of net sales.

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The underlying gross margin decreased by 0.6 percentage points (cc) mainly driven by increased royalties. Functional costs which include General & Administration, Marketing & Sales and R&D expenses improved by 2.0 percentage points, driven by productivity gains in Marketing & Sales and R&D despite significant investments in new product launches. Other Income & Expense, net, remained flat in constant currencies.

#### Alcon

In 2011, Alcon operating income increased 85% to \$1.5 billion on a restated basis. Since however the 2010 base only includes Alcon, Inc. from August 25, 2010, as indicated above, a comparison on a 2010 pro forma basis is more meaningful.

Operating income in 2011 of \$1.5 billion rose 24% (+14% cc) on a pro forma basis. Operating income was impacted by the inclusion of exceptional income from a litigation settlement (\$183 million), amortization of intangible assets (\$1.9 billion), integration costs (\$221 million), and the impact of manufacturing optimization (\$57 million).

Core operating income in 2011 of \$3.5 billion increased by 13% (+9% cc) on a pro forma basis. Core operating income margin in constant currencies increased by 0.7 percentage points on a pro forma basis. In addition, there was a positive currency impact of 0.1 percentage points, resulting in a net increase in core operating income margin of 0.8 percentage points to 35.1% of net sales.

#### Sandoz

Operating income grew 8% (+10% cc) over the prior year to \$1.4 billion. The operating income margin improved by 0.5 percentage points in constant currencies, more than offset by a negative currency impact of 0.9 percentage points, resulting in a net decrease of 0.4 percentage points to 15.0% of net sales. The constant currency margin improvement was the result of productivity improvements, the addition of the Falcon business and income from reduction of a contingent consideration obligation, partly offset by charges and provisions for legal cases in the US (\$204 million) as well as price erosion.

In 2011, core operating income rose 10% (+11% cc) to \$1.9 billion, as declining prices were more than offset by additional sales volume, new product launches and productivity improvements in all areas. Core operating income margin in constant currencies increased by 0.8 percentage points to 21.2% of net sales. Currency had a negative impact, resulting in a 20.3% core operating income margin.

#### Vaccines and Diagnostics

Operating loss was \$249 million for 2011 compared to an operating income of \$612 million in 2010, due in large part to the operating income associated with A(H1N1) pandemic flu vaccine sales from the prior year not repeated in 2011.

Excluding the impact of A(H1N1), profitability improved, despite continued investment in our pipeline and meningococcal disease franchise, driven by solid underlying sales growth. 2011 included impairments of \$143 million related to financial and intangible assets compared to \$98 million in 2010; 2010 also included charges related to a legal settlement of \$45 million and restructuring charges of \$52 million.

Core operating income for the year was \$135 million compared to \$1.1 billion for 2010. Excluding the impact of A(H1N1), core operating income also improved over 2010.

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#### Consumer Health

Operating income for 2011 decreased 7% to \$727 million (but increased 4% cc), with operating income margin in constant currencies increasing by 0.2 percentage points, more than offset by a negative currency impact of 2.3 percentage points, resulting in an operating income margin of 15.7% of net sales.

Core operating income in 2011 increased by 3% (+12% cc) to \$873 million. Core operating income excludes the \$115 million exceptional charge related to the product recall. Core operating income margin in constant currencies increased by 1.8 percentage points. This result demonstrates strong operating leverage with core operating income growing significantly ahead of net sales. \$73 million of the product recall exceptional charge relates to sales returns. As no corresponding adjustment was made at the net sales level, it had a beneficial impact of 0.4 percentage points on the core operating income margin. Currency negatively impacted core operating income margin by 2.3 percentage points, resulting in a net core operating income margin decrease of 0.5 percentage points to 18.9% of net sales.

Gross margin improved slightly by 0.1 percentage points (cc) driven by productivity gains that were partially offset by product mix. Marketing & Sales expenses decreased by 0.7 percentage points (cc) versus prior year driven by efficiency improvements in OTC partially offset by increased investment in the Animal Health business. R&D expenses decreased by 0.1 percentage points (cc) from productivity measures that more then offset continued investment in innovation. General & Administrative expenses decreased by 0.2 percentage points (cc) due to strong cost control. Other Income and Expense, net, improved by 0.3 percentage points (cc) largely driven by income from smaller product divestments.

#### Corporate Income & Expense, Net

Corporate income & expense, net, includes the costs of Group headquarters. These net expenses of \$670 million in 2011 were 48% higher than in 2010 primarily due to an exceptional pension curtailment gain of \$265 million in the prior year.

#### **Non-Operating Income and Expense**

	Year ended Dec 31, 2011	Year ended Dec 31, 2010	Change in \$	Change in constant currencies
	\$ m	\$ m	%	%
Operating income	10,998	11,526	(5)	1
Income from associated companies	528	804	(34)	(34)
Interest expense	(751)	(692)	9	5
Other financial income and expense	(2)	64	(103)	(140)
Income before taxes	10,773	11,702	(8)	(2)
Taxes	(1,528)	(1,733)	(12)	(6)
Group net income	9,245	9,969	(7)	(2)
Attributable to:				
Shareholders of Novartis AG	9,113	9,794	(7)	(1)
Non-controlling interests	132	175	(25)	(25)
Basic EPS (\$)	3.83	4.28	(11)	(5)
,		138		

# **Core Non-Operating Income and Expense**

	Year ended Dec 31, 2011	Year ended Dec 31, 2010	Change in \$	Change in constant currencies	
	\$ m	\$ m	%	%	
Core operating income	15,909	14,006	14	16	
Income from associated companies	779	1,041	(25)	(28)	
Interest expense	(751)	(692)	9	5	
Other financial income and expense	(2)	64	(103)	(140)	
Core income before taxes	15,935	14,419	11	13	
Taxes	(2,445)	(2,390)	2	5	
Core net income	13,490	12,029	12	15	
Attributable to:					
Shareholders of Novartis AG	13,273	11,767	13	16	
Non-controlling interests	217	262	(17)	(17)	
Core basic EPS (\$)	5.57	5.15	8	11	
T					

**Income from Associated Companies** 

Associated companies are accounted for using the equity method generally when Novartis holds between 20% and 50% of the voting shares of these companies, or where Novartis has otherwise significant influence over them. Income from associated companies is mainly derived from the Group's investments in Roche Holding AG and, prior to August 25, 2010, Alcon.

The income from associated companies fell from \$804 million in 2010 to \$528 million in 2011, as since August 25, 2010 Alcon, Inc. is fully consolidated and no longer accounted for as an associated company.

The following is a summary of the individual components included in the income from associated companies:

	2011	2010
	\$ m	\$ m
Share of estimated Roche reported net income	702	648
Restructuring impact (2011 includes \$41 million from 2010; 2010 includes \$43 million from 2009)	(41)	(132)
Amortization of intangible assets	(162)	(136)
Net income effect from Roche	499	380
Share of Alcon net income		385
Catch-up for actual Alcon previous year net income		2
Revaluation of initial 25% interest to fair value		378
Recycling of losses accumulated in comprehensive income from July 7, 2008 to August 25, 2010		(43)
Amortization of intangible assets		(289)
Net income effect from Alcon (in 2010 up to August 25, 2010)		433
Net income from other associated companies	29	(9)
Income from associated companies	528	804
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The Group's 33.3% interest in Roche's voting shares, which represents a 6.3% interest in Roche's total equity, generated income of \$499 million in 2011, up from \$380 million in 2010. The 2011 contribution reflects an estimated \$702 million share of Roche's net income in 2011. This contribution, however, was reduced by \$162 million for the amortization of intangible assets arising from the allocation of the purchase price paid by Novartis for this investment to Roche's intangible assets and an exceptional charge of \$41 million taken in 2011 as part of Roche's restructuring charges.

The 2010 result from Alcon includes the net income up to August 25, 2010 of \$385 million and a positive prior-year adjustment of \$2 million which were reduced by \$289 million for the amortization of intangible assets.

Adjusting for the exceptional items in both years, core income from associated companies decreased 25% to \$779 million.

A survey of analyst estimates is used to estimate the Group's share of net income in Roche. Any differences between these estimates and actual results will be adjusted in the 2012 consolidated financial statements.

#### Interest Expense and other Financial Income/Expense

In 2011, interest expense increased by 9% from \$692 million to \$751 million. Other financial income/expense was a net expense of \$2 million, down from a net income of \$64 million in the prior year mainly due to lower earnings from investments as a result of the decreased average liquidity. The currency result remained stable.

#### Taxes

Tax expenses in 2011 were \$1.5 billion, a 12% (6% cc) decrease from 2010. The tax rate (taxes as a percentage of income before taxes) decreased to 14.2% in 2011 from 14.8% in 2010 mainly due to the favorable impact of the Alcon, Inc. merger and as a result the ability to undertake a related tax structure reorganization. For the same reason the core tax rate (taxes as percentage of core income before taxes) decreased to 15.3% in 2011 from 16.6% in 2010. The effective tax rate is different to the expected tax rate due to various adjustments made to the IFRS results to arrive at taxable income. For further information on the main elements contributing to the difference, see " Core Results as Defined by Novartis" and "Item 18. Financial Statements note 6".

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our principal accounting policies are set out in note 1 to the Group's consolidated financial statements, which are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

Given the uncertainties inherent in our business activities, we must make certain estimates and assumptions that require difficult, subjective and complex judgments. Because of uncertainties inherent in such judgments, actual outcomes and results may differ from our assumptions and estimates which could materially affect the Group's consolidated financial statements. Application of the following accounting policies requires certain assumptions and estimates that have the potential for the most significant impact on our consolidated financial statements.

### **Deductions from Revenues**

As is typical in the pharmaceuticals industry, our gross sales are subject to various deductions which are composed primarily of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales

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deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales.

The following summarizes the nature of some of these deductions and how the deduction is estimated. After recording these, net sales represent our best estimate of the cash that we expect to ultimately collect. The United States market has the most complex arrangements related to revenue deductions.

#### United States specific healthcare plans and program rebates

The United States Medicaid Drug Rebate Program is administered by State governments using State and Federal funds to provide assistance to certain vulnerable and needy individuals and families. Calculating the rebates to be paid involves interpreting relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, product price increases and the mix of contracts and specific terms in the individual State agreements. These provisions are adjusted based on established processes and experiences from re-filing data with individual States.

The United States Federal Medicare program, which funds healthcare benefits to individuals age 65 or older, provides prescription drug benefits under Part D of the program. This benefit is provided through private prescription drug plans. Provisions for estimating Medicare Part D rebates are calculated based on the terms of individual plan agreements, product sales and population growth, product price increases and the mix of contracts and adjusted periodically.

We offer rebates to key managed healthcare plans to sustain and increase market share for our products. These rebate programs provide payors a rebate after they attain certain performance parameters related to product purchases, formulary status or pre-established market share milestones relative to competitors. These rebates are estimated based on the terms of individual agreements, historical experience and projected product growth rates. We adjust provisions related to rebates periodically to reflect actual experience.

There is often a time lag of several months between us recording the revenue deductions and our final accounting for them.

#### Non-United States specific healthcare plans and program rebates

In certain countries other than the United States we provide rebates to governments and other entities. These rebates are often mandated by laws or government regulations.

In several countries we enter into innovative pay-for-performance arrangements with certain healthcare providers, especially in Europe and Australia. Under these agreements, we may be required to make refunds to the healthcare providers or to provide additional medicines free of charge if anticipated treatment outcomes do not meet predefined targets. Potential refunds and the delivery of additional medicines at no cost are estimated and recorded as a deduction of revenue at the time the related revenues are recorded. Estimates are based on historical experience and clinical data. In cases where historical experience and clinical data are not sufficient for a reliable estimation of the outcome, revenue recognition would be deferred until such history would be available.

There is often a time lag of several months between us recording the revenue deductions and our final accounting for them.

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#### Non-healthcare plans and program rebates, returns and other deductions

Charge-backs occur where our subsidiaries have arrangements with indirect customers to sell products at prices that are lower than the price charged to wholesalers. A chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contract price. We account for vendor charge-backs by reducing revenue by an amount equal to our estimate of charge-backs attributable to a sale and they are generally settled within one to three months of incurring the liability. Provisions for estimated charge-backs are calculated using a combination of factors such as historical experience, product growth rates, payments, level of inventory in the distribution channel, the terms of individual agreements and our estimate of the claims processing time lag.

We offer rebates to purchasing organizations and other direct and indirect customers to sustain and increase market share for our products. Since rebates are contractually agreed upon, rebates are estimated based on the terms of individual agreements, historical experience, and projected product growth rates.

When we sell a product providing a customer the right to return a product, we record a provision for estimated sales returns based on our sales returns policy and historical rates. Other factors considered include product recalls, expected marketplace changes and the remaining shelf life of the product, and the entry of generic products. In 2012, sales returns amounted to approximately 1% of gross product sales. If sufficient experience is not available, sales are only recorded based on evidence of product consumption or when the right of return has expired.

We enter into distribution service agreements with major wholesalers, which provide a financial disincentive for wholesalers to purchase product quantities exceeding current customer demand. Where possible, we adjust shipping patterns for our products to maintain wholesalers' inventories level consistent with underlying patient demand.

We offer cash discounts to customers to encourage prompt payment. Cash discounts are accrued at the time of invoicing and deducted from revenue.

Following a decrease in the price of a product, we generally grant customers a "shelf stock adjustment" for a customer's existing inventory for the involved product. Provisions for shelf stock adjustments, which are primarily relevant within the Sandoz Division, are determined at the time of the price decline or at the point of sale if a price decline can be reasonably estimated based on inventory levels of the relevant product.

Other sales discounts, such as consumer coupons and co-pay discount cards, are offered in some markets. These discounts are recorded at the time of sale, or when the coupon is issued and are estimated utilizing historical experience and the specific terms for each program. If a discount for a probable future transaction is offered as part of a sales transaction then an appropriate portion of revenue is deferred to cover this estimated obligation.

We adjust provisions for revenue deductions periodically to reflect actual experience. To evaluate the adequacy of provision balances, we use internal and external estimates of the level of inventory in the distribution channel, actual claims data received and the time lag for processing rebate claims. Management also estimates the level of inventory of the relevant product held by retailers and in transit. External data sources include reports of wholesalers and third-party market data purchased by Novartis.

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The following table shows the worldwide extent of our revenue deductions provisions and related payment experiences:

## PROVISIONS FOR REVENUE DEDUCTIONS

	Revenue deductions			Income st	rge	Change in provisions offset against	Revenue deductions
	provisions at January 1 c	and business ombination	A Payments/ sutilizations	djustments of prior years	Current year		provisions at December 31
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
2012							
US specific healthcare plans and program rebates	1,440	17	(3,191)	(46)	3,222		1,442
Non-US specific healthcare plans and program rebates	766	15	(1,423)	94	1,514		966
Non-healthcare plans and program related rebates, returns and other deductions	1,536	176	(7,324)	(143)	7,509	(90)	1,664
Total 2012	3,742	208	(11,938)	(95)	12,245	(90)	4,072
2011				(4.2)			
US specific healthcare plans and program rebates	1,162		(2,860)	(19)	3,157		1,440
Non-US specific healthcare plans and program	575	(2.1)	(1.042)	(22)	1.001		7.00
rebates	575	(24)	(1,043)	(23)	1,281		766
Non-healthcare plans and program related rebates, returns and other deductions	1,360	(68)	(6,846)	(7)	7,324	(227)	1,536
Total 2011	3,097	(92)	(10,749)	(49)	11,762	(227)	3,742
2010							
US specific healthcare plans and program rebates	755	226	(1,949)	(8)	2,138		1,162
Non-US specific healthcare plans and program							
rebates	455	(34)	(444)	(9)	607		575
Non-healthcare plans and program related rebates, returns and other deductions	884	163	(5,779)	(32)	6,056	68	1,360
Total 2010	2,094	355	(8,172)	(49)	8,801	68	3,097

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The table below shows the gross to net sales reconciliation for our Pharmaceuticals Division:

#### GROSS TO NET SALES RECONCILIATION

	Charged through revenue deduction provisions	cment charge Charged directly without being recorded in revenue deduction provisions \$ m	Total \$ m	In % of gross sales
2012				
Pharmaceuticals gross sales subject to deductions			39,912	100.0
US specific healthcare plans and program rebates	(2,358)		(2,358)	(5.9)
Non-US specific healthcare plans and program rebates	(1,096)	(842)	(1,938)	(4.8)
Non-healthcare plans and program related rebates, returns and other deductions	(1,579)	(1,884)	(3,463)	(8.7)
Total Pharmaceuticals gross to net sales adjustments	(5,033)	(2,726)	(7,759)	(19.4)
Pharmaceuticals net sales 2012			32,153	80.6
2011				
Pharmaceuticals gross sales subject to deductions			40,004	100.0
US specific healthcare plans and program rebates	(2,424)		(2,424)	(6.0)
Non-US specific healthcare plans and program rebates	(801)	(408)	(1,209)	(3.0)
Non-healthcare plans and program related rebates, returns and other deductions	(1,631)	(2,232)	(3,863)	(9.7)
Total Pharmaceuticals gross to net sales adjustments	(4,856)	(2,640)	(7,496)	(18.7)
Pharmaceuticals net sales 2011			32,508	81.3
2010				
Pharmaceuticals gross sales subject to deductions			36,400	100.0
US specific healthcare plans and program rebates	(2,029)		(2,029)	(5.6)
Non-US specific healthcare plans and program rebates	(298)	(263)	(561)	(1.5)
Non-healthcare plans and program related rebates, returns and other deductions	(1,585)	(1,919)	(3,504)	(9.6)
Total Pharmaceuticals gross to net sales adjustments	(3,912)	(2,182)	(6,094)	(16.7)
Pharmaceuticals net sales 2010			30,306	83.3

## Impairment of Goodwill, Intangible Assets and Property, Plant and Equipment

We review long-lived intangible assets and property, plant and equipment for impairment whenever events or changes in circumstance indicate that the asset's balance sheet carrying amount may not be recoverable. Goodwill, the Alcon brand-name and other currently not amortized intangible assets are reviewed for impairment at least annually.

An asset is generally considered impaired when its balance sheet carrying amount exceeds its estimated recoverable amount, which is defined as the higher of its fair value less costs to sell and its value in use. Usually, Novartis adopts the fair value less costs to sell method for its impairment tests. In most cases no directly observable market inputs are available to measure the fair value less costs to sell.

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Therefore an estimate of fair value less costs to sell is derived indirectly and is based on net present value techniques utilizing post-tax cash flows and discount rates. In the limited cases where the value in use method is applied, net present value techniques are utilized using pre-tax cash flows and discount rates.

Fair value reflects estimates of assumptions that market participants would be expected to use when pricing the asset and for this purpose management considers the range of economic conditions that are expected to exist over the remaining useful life of the asset. The estimates used in calculating net present values are highly sensitive, and depend on assumptions specific to the nature of the Group's activities with regard to:

the amount and timing of projected future cash flows;

future tax rates;

the behavior of competitors (launch of competing products, marketing initiatives, etc.); and

an appropriate discount rate.

Due to the above factors, actual cash flows and values could vary significantly from forecasted future cash flows and related values derived using discounting techniques.

The recoverable amount of a cash-generating unit and related goodwill is usually based on the fair value less costs of sale derived from applying discounted future cash flows based on the key assumptions in the following table:

	Pharmaceuticals	Alcon	Sandoz	Vaccines and Diagnostics	Consumer Health
	%	%	%	%	%
Sales growth rate assumptions after forecast					
period	1.6	3	0 to 2	0.5	0 to 2
Discount rate (post-tax)	7	7	7	7	7

In 2012, intangible asset impairment charges of \$286 million were recognized. These relate to impairment charges of \$211 million in the Pharmaceuticals Division. Novartis also recorded various impairment charges of \$75 million in all other Divisions.

In 2011, intangible asset impairment charges of \$627 million were recorded. \$552 million of these arose in the Pharmaceuticals Division, principally due to the expected reduction in demand for *Tekturna/Rasilez* (aliskiren) and discontinuation of PRT128 (elinogrel), SMC021 (oral calcitonin), PTK796 and AGO178 (agomelatine) development programs. \$75 million of impairment charges arose in all other Divisions.

Reversal of prior year impairment charges amounted to \$3 million (2011: \$8 million).

The amount of goodwill and other intangible assets on our consolidated balance sheet has increased significantly in recent years, primarily due to acquisitions. Although no significant additional impairments are currently anticipated, impairment testing could lead to material impairment charges in the future. For more information, see "Item 18. Financial Statements" note 11".

Additionally, impairment charges for property, plant and equipment during 2012 amounted to \$39 million (2011: \$413 million of which \$403 million was in Pharmaceuticals primarily related to the expected reduction in demand for *Tekturna/Rasilez* and the discontinuation of the SMC021 development program).

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#### **Trade Receivables**

Trade receivables are initially recognized at their invoiced amounts including any related sales taxes less adjustments for estimated revenue deductions such as rebates, chargebacks and cash discounts.

Provisions for doubtful trade receivables are established once there is an indication that it is likely that a loss will be incurred and represents the difference between the receivable value in the balance sheet and the estimated net collectible amount. Significant financial difficulties of a customer, such as probability of bankruptcy or financial reorganization or default/delinquency in payments are considered indicators that recovery of the trade receivable is doubtful. Trade receivable balances include sales to drug wholesalers, retailers, private health systems, government agencies, managed care providers, pharmacy benefit managers and government-supported healthcare systems. Novartis continues to monitor sovereign debt issues and economic conditions in Greece, Italy, Portugal, Spain and other countries in Europe and evaluates accounts receivable in these countries for potential collection risks. Substantially all of the trade receivables overdue from such countries are due directly from local governments or from government-funded entities. Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time that it takes to collect these accounts receivable and may require Novartis to re-evaluate the collectability of these receivables in future periods.

#### Retirement and other post-employment benefit plans

We sponsor pension and other post-employment benefit plans in various forms that cover a significant portion of our current and former associates. For post-employment plans with defined benefit obligations, we are required to make significant assumptions and estimates about future events in calculating the expense and the present value of the liability related to these plans. These include assumptions about the discount rates we apply to estimate future liabilities, expected returns on plan assets and rates of future pension 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 the Group may differ materially from the actual results we experience due to changing market and economic conditions, higher or lower withdrawal rates, or longer/shorter life spans of participants among other factors. For example, a decrease in the discount rate we apply in determining the present value of the obligations of a quarter of one percent would have increased our year-end defined benefit pension obligation for plans in Switzerland, United States, UK, Germany and Japan, which represent about 95% of the Group total defined benefit pension obligation, by approximately \$0.8 billion. If the 2012 discount rate had been a quarter of one percentage point lower than actually assumed, net periodic pension cost for pension plans, in these countries, which represent about 75% of the Group's total net periodic pension cost for pension plans, would have decreased by approximately \$13 million, and if the same decrease was also assumed for the expected return on plan assets for pension plans in these five countries would have decreased by approximately \$39 million. Depending on events, such differences could have a material effect on our total equity. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 18. Financial Statements" note 25".

#### **Contingencies**

A number of our subsidiaries are involved in various government investigations and legal proceedings (intellectual property, product liability, commercial, employment and wrongful discharge, environmental claims, etc.) arising out of the normal conduct of their businesses. For more information, see "Item 18. Financial Statements" note 20" to the Group's consolidated financial statements.

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We record accruals for contingencies when it is probable that a liability has been incurred and the amount can be reliably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a significant portion of the overall accrual is actuarially determined based on factors such as past experience, amount and number of claims reported, and estimates of claims incurred but not yet reported. We provide for individually significant cases when probable and the amount can be reliably estimated. Expected legal defense costs are accrued when the amount can be reliably estimated.

In some instances, the inherent uncertainty of litigation, the resources required to defend against governmental actions, the potential impact on our reputation, and the potential for exclusion from United States federal and other government reimbursement programs have contributed to decisions by companies in our industry to enter into settlement agreements with governmental authorities. These settlements have had in the past, and may continue in the future, to involve large cash payments, including potential repayment of amounts that were allegedly improperly obtained and other penalties including treble damages. In addition, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

Provisions are recorded for environmental remediation costs when expenditure on remedial work is probable and the cost can be reliably estimated. Remediation costs are provided for under "Non-current liabilities" in the Group's consolidated balance sheet. They are estimated by calculating the present value of expected costs. Provisions relating to estimated future expenditure for liabilities do not usually reflect any insurance or other claims or recoveries, since these are only recognized as assets when the amount is reasonably estimable and collection is virtually certain.

#### Research & Development

Internal Research & Development costs are fully charged to the consolidated income statement in the period in which they are incurred. We consider that regulatory and other uncertainties inherent in the development of new products preclude the capitalization of internal development expenses as an intangible asset usually until marketing approval from the regulatory authority is obtained in a relevant major market, such as for the United States, the European Union, Switzerland or Japan.

### **Healthcare Contributions**

In many countries our subsidiaries are required to make contributions to the countries' healthcare costs as part of programs other than the ones mentioned under deductions from revenue above. The amounts to be paid depend on various criteria such as the sales volume compared to certain targets, compared to the competition or to the Group's market share. There is considerable judgment required in estimating these contributions. The most important healthcare contributions relate to the United States Healthcare Reform fee which was introduced in 2011. This fee is an annual fee to be paid by pharmaceutical companies based on the prior year's government program sales. Effective 2013, the United States government has also implemented a medical device sales tax which is expected to be applicable to Alcon's United States sales of products that are considered surgical devices under the respective act. The Pharmaceutical fee and the Medical Device Tax are recorded in "Other expenses" since they are considered to be an indirect tax or in inventory and cost of goods sold when the tax is levied on intercompany sales. The annual expense for these United States taxes is approximately \$150 million.

#### **Taxes**

We prepare and file our tax returns based on an interpretation of tax laws and regulations, and record estimates based on these judgments and interpretations. Our tax returns are subject to examination by the competent taxing authorities, which may result in an assessment being made requiring payments of additional tax, interest or penalties. Inherent uncertainties exist in our estimates of our tax positions. We

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believe that our estimated amounts for current and deferred tax assets or liabilities, including any amounts related to any uncertain tax positions, are appropriate based on currently known facts and circumstances.

#### **New Accounting Pronouncements**

See "Item 18. Financial Statements note1".

#### EFFECTS OF CURRENCY FLUCTUATIONS

We transact our business in many currencies other than the US dollar, our reporting currency.

The following provides an overview of net sales and expenses for 2012 and 2011 for currencies most important to the Group:

Currency		2012	2011	2010
		%	%	%
US dollar (\$)	Net sales	36	36	36
	Operating expenses	39	38	36
Euro (EUR)	Net sales	25	27	28
	Operating expenses	25	25	26
Swiss franc (CHF)	Net sales	2	2	2
	Operating expenses	13	14	13
Japanese yen (JPY)	Net sales	9	9	8
	Operating expenses	5	4	4
Other currencies	Net sales	28	26	26
	Operating expenses	18	19	21

We prepare our consolidated financial statements in US dollars. As a result, fluctuations in the exchange rates between the US dollar and other currencies can have a significant effect on both the Group's results of operations as well as on the reported value of our assets, liabilities and cash flows. This in turn may significantly affect reported earnings (both positively and negatively) and the comparability of period-to-period results of operations.

For purposes of our consolidated balance sheets, we translate assets and liabilities denominated in other currencies into US dollars at the prevailing market exchange rates as of the relevant balance sheet date. For purposes of the Group's consolidated income and cash flow statements, revenue, expense and cash flow items in local currencies are translated into US dollars at average exchange rates prevailing during the relevant period. As a result, even if the amounts or values of these items remain unchanged in the respective local currency, changes in exchange rates have an impact on the amounts or values of these items in our consolidated financial statements.

We seek to manage currency exposure by engaging in hedging transactions where management deems appropriate, after taking into account the natural hedging afforded by our global business activity. For 2012, we entered into various contracts that change in value with movements in foreign exchange rates in order to preserve the value of assets, commitments and expected transactions. We also use forward contracts and foreign currency options to hedge expected net revenues in foreign currencies. For more information on how these transactions affect our consolidated financial statements and on how foreign exchange rate exposure is managed, see "Item 18. Financial Statements notes 1, 5 and 29" to the Group's consolidated financial statements.

There is however, also a risk that certain countries could devalue their currency. If this occurs then it could impact the effective prices we would be able to charge for our products and also have an adverse

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impact on both our consolidated income statement and currency translation adjustments included in our consolidated equity.

The average value of the US dollar in 2012 increased against the EUR, CHF, and GBP. The following table sets forth the foreign exchange rates of the US dollar against these currencies, used for foreign currency translation when preparing the Group's consolidated financial statements:

	Avera	ge for				
	yea	ır	Change	Year	-end	Change
\$ per unit	2012	2011	in %	2012	2011	in %
EUR	1.286	1.392	(8)	1.319	1.294	2
CHF	1.067	1.130	(6)	1.093	1.064	3
GBP	1.585	1.603	(1)	1.616	1.543	5
JPY (100)	1.254	1.255	0	1.161	1.289	(10)

	Averaş yea	-	Change	Year	-end	Change
\$ per unit	2011	2010	in %	2011	2010	in %
EUR	1.392	1.327	5	1.294	1.324	(2)
CHF	1.130	0.961	18	1.064	1.063	0
GBP	1.603	1.546	4	1.543	1.552	(1)
JPY (100)	1.255	1.141	10	1.289	1.227	5

The following table provides a summary of the currency impact on key Group figures due to their conversion into \$, the Group's reporting currency, of the financial data from entities reporting in non-US dollars. Constant currency (cc) calculations apply the exchange rates of the prior year to the current year financial data for entities reporting in non-US dollars. For further detail, see "Non-IFRS measures as defined by Novartis".

#### **CURRENCY IMPACT ON KEY FIGURES**

	Change			Change		
	in constant	Change	Percentage point	constant	Change	Percentage point
	currencies %	in \$ %	currency impact	currencies %	in \$ %	currency impact
	2012	2012	2012	2011	2011	2011
Net sales	0	(3)	(3)	12	16	4
Operating income	8	5	(3)	1	(5)	(6)
Net income	7	4	(3)	(2)	(7)	) (5)
Core operating						
income	(2)	(5)	(3)	16	14	(2)
Core net income	(3)	(5)	(2)	15	12	(3)
	1	. ` `				

For additional information on the effects of currency fluctuations, see "Item 18. Financial statements" note 29".

### FACTORS AFFECTING RESULTS OF OPERATIONS

A number of key factors influence the Group's results of operations and the development of our businesses.

We believe that healthcare remains a growth industry, driven by the rapid aging of the global population, expanding access to healthcare in emerging markets and advances in science and technology that create opportunities to improve health outcomes and enhance quality of life for patients worldwide. At the same time, challenging business and regulatory conditions continue to impede growth across the healthcare industry.

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As the only healthcare company with leading positions in pharmaceuticals, eye care, generics, vaccines and diagnostics, over-the-counter medicines and animal health, we believe that Novartis is well-positioned to capture opportunities and mitigate risks across the healthcare landscape. We expect that our continued focus on innovation, growth and productivity across our broad, diversified portfolio will allow us to meet the evolving needs of patients and healthcare systems worldwide.

#### **Transformational Changes Fueling Demand**

Long-term trends in the composition and behavior of the worldwide population, as well as ongoing innovation in science and technology, are driving demand for and access to healthcare. These changes present opportunities for Novartis to expand its presence in new and established markets and meet the changing demands of patients around the world.

#### Aging Population and Shifting Behaviors

As the global life expectancy continues to rise, the UN Population Fund projects that the total number of people over 60 will exceed 1 billion worldwide in the next decade, an increase of approximately 200 million over 2012. By 2050, the over-60 population will be larger than the under-15 population, according to the United Nations Population Fund. This aging of the global population has accelerated demand for treatments addressing diseases and conditions such as glaucoma, cataracts and wet age-related macular degeneration, among other eye diseases, which Novartis offers treatments to address that disproportionately afflict the elderly.

At the same time, due to increasing economic prosperity and shifting nutritional habits, the global incidence of obesity is rising, and is now more than double the rate it was in 1980, according to the World Health Organization (WHO). This trend is particularly evident in dynamic, emerging markets: China, for example, has seen its number of obese people quintuple since 2005 to nearly 100 million today, according to Chinese government statistics.

Increased rates of obesity, as well as habits such as cigarette smoking and sedentary lifestyles, have, in turn, boosted the prevalence of chronic diseases including cardiovascular disease, diabetes and chronic respiratory diseases which now account for more than 60% of all deaths worldwide, according to the WHO. Novartis businesses, particularly Pharmaceuticals, Alcon and Sandoz, offer products that help patients suffering from chronic diseases, and we plan to continue to make investments in new treatments to address these growing health threats.

#### Global Rise in Healthcare Spending Led by Emerging Markets

Despite a difficult economic environment, global healthcare spending continues to climb, and is projected to reach nearly \$1.2 trillion by 2016, according to industry research firm IMS Health.

While the US continues to outstrip all other countries in terms of healthcare expenditures, emerging markets are contributing an increasing proportion of total global spend. Driven by rising incomes, continued low cost for drugs and government sponsored programs to increase access to treatments, emerging markets are expected to double their spending on pharmaceuticals over the next five years and contribute 30% of global healthcare expenditures by 2016, according to IMS Health. Developed markets, by contrast, are expected to account for 57% of global healthcare spending in 2016, down from 73% in 2006.

Reflecting the importance of emerging markets within the Novartis growth strategy, we continue to expand our presence, not only in the so-called BRIC countries (Brazil, Russia, India and China), which are well-known to be large and growing markets, but in other fast-growing markets as well. The Middle East, for example, has become a growth engine for Novartis, due in part to our investments in Egypt, Saudi Arabia and the United Arab Emirates, where our Pharmaceuticals Division is growing ahead of the market. We also signed a Memorandum of Understanding with the Government of Malaysia to help

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strengthen the country's healthcare capabilities. Our collaboration, the first of its kind in Malaysia, will likely include building technical capabilities, promoting clinical trials, expanding access to innovative medicines and quality generic products, and supporting healthcare start-up companies through the Novartis Venture Fund.

#### Scientific Advances Opening New Opportunities for Targeted Therapies

With scientific advances, there is a growing opportunity to personalize healthcare for individual patients to improve results and reduce costs. For example, it is estimated that up to 95% of the variability in patient drug response may be due to genetic differences, according to scientific studies. Tailoring treatments based on specific biological factors, or "biomarkers," that indicate whether or not a given drug will be effective for a particular patient can significantly enhance response rates and outcomes while reducing costs associated with unnecessary or ineffective treatments. The market for personalized medicine is expected to be a major growth driver for the industry, with around 11% annual growth projected in the coming years, according to PricewaterhouseCoopers.

Advancing personalized medicine is central to our overall drug discovery and development strategy. In 2012, we realigned our Molecular Diagnostics unit and embedded it within Oncology Global Development to coordinate the development of innovative new treatments for patients with cancers and other diseases, with the development of tests, also known as companion diagnostics, to pinpoint the patients who are most likely to benefit from those treatments. Our diagnostics function, now known as Companion Diagnostics (CDx), is responsible for developing and manufacturing regulated diagnostic tests and registrational assays for pivotal clinical trials across the Pharmaceuticals portfolio.

Also within our Pharmaceuticals Division, Genoptix Medical Laboratory, which we acquired in 2011, continues to provide comprehensive laboratory services to US community-based hematologists and oncologists, advancing their ability to define and monitor individualized treatment programs.

Additionally, across our R&D activities at NIBR and Sandoz, we require that all proposals for new drug targets include a "path to the clinic." This often includes a biomarker discovery phase to identify which individuals will benefit most from a potential treatment and which might have a negative or no response, helping direct medical decision-making and subsequent therapy assessments for patients.

#### New Technologies Changing the Delivery of Healthcare

The rise of social and mobile technology is making it easier for patients, providers and payors to address healthcare needs quickly and efficiently. For example, according to PricewaterhouseCoopers, one in three patients have sought information about other patient experiences with their disease and one in four have posted their health experience to social networks. On the provider side, more than 60% of physicians in the United States were using tablet computers as of May 2012, up from 35% a year previously (according to healthcare market research firm Manhattan Research), to research medical treatments and access electronic health records.

Health applications on mobile phones, known as mHealth applications, have also provided a low-cost, real-time way to track disease progression and facilitate communication with patients, providers and payors. The data collected through these applications are more reliable than self-reporting from patients and can help scientists and doctors gather evidence to guide their investigations and tailor treatment regimens for individual patients. Additionally, when mHealth applications are used in combination with GPS data, they can support early detection and warning systems for global outbreaks of illnesses related to environmental exposures or infectious agents. As applications like these continue to proliferate and advance, according to business intelligence firm Global Data, the global mHealth market is set to jump in value by around 40% to \$11.7 billion in 2018, potentially changing the delivery of health services and providing Novartis with more opportunities to reach patients and improve quality of care.

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Through our eHealth program, Novartis is using emerging technologies to radically rethink the way we deliver products and services to patients, doctors and payors. For example, we developed a medical patch for *Exelon*, our Alzheimer's treatment, that integrates an electronic chip to signal when it is time for a replacement. Similarly, work is progressing on a proprietary smart inhaler for COPD patients, the "eBreezhaler," which sends reminders and motivational messages based on actual patient behavior to help improve adherence and outcomes.

#### Shift to Generics and OTC Products

While healthcare costs continue to rise as a percentage of GDP in countries around the world, consumer demand for affordable products both in developed and developing economies has also increased. The global generics industry has grown by roughly 9% per year on average between 2007 and 2011, according to industry research firm MarketLine, significantly higher than the equivalent growth rate for pharmaceuticals, and will likely accelerate as healthcare systems encourage the use of generics to keep costs down.

Similarly, over-the-counter products, which in the United States are used on a regular basis by 35% of adults (according to the American College of Preventative Medicine), have also seen an increase in demand (as calculated by market research firm Kalorama Information). With leadership positions in both generics and over-the-counter medicines, we believe that Novartis is well-positioned to take advantage of these trends.

#### **Increasingly Challenging Business Environment**

While demographic and socioeconomic trends, as well as scientific and technological innovation, have created valuable opportunities for us to grow our business and improve the health of patients globally, significant challenges continue to pressure the industry.

#### Patent Expirations and Generic Competition Pressuring Industry

It is estimated that between 2013 and 2016, drugs worth \$156 billion in sales globally will lose market exclusivity, according to pharmaceutical sector research firm EvaluatePharma. In Japan, which has historically had relatively low generic penetration, generic drugs accounted for more than 25% an all-time high of the domestic prescription medicines market in 2012, according to the Japan Generic Medicines Association. In the weeks and months following patent expiry, sales of brand-name drugs typically fall dramatically, by as much as 90% in some markets.

The ability to secure and defend our intellectual property is particularly crucial for our Pharmaceuticals and Alcon divisions, where the loss of patent protection on one or more products can have a material effect on the Group's results of operations. To counter these challenges, Novartis focuses on innovating in areas of unmet patient need in order to rejuvenate the portfolio with new products and therapies. We expect revenue from recently launched products (products launched since 2007, except Sandoz products launched in last 24 months), which comprised 29% of net sales in 2012, to balance the impact of patent loss. We also take legally permissible steps to defend our intellectual property rights, including initiating patent infringement lawsuits against generic drug manufacturers.

Some of our best-selling products have begun to face considerable competition due to expiration of their patent protection:

The patent on valsartan, the active ingredient of *Diovan/Co-Diovan/Diovan HCT* (high blood pressure), expired in the major countries of the European Union in November 2011, and generic competitors have launched there. In addition, patent protection expired in the United States in September 2012, and generic versions of *Diovan HCT* have launched in the United States. Generic versions of *Diovan* monotherapy have not yet launched but could potentially launch at any time. In addition, patent protection for valsartan is scheduled to expire in Japan in 2013 and 2016 for *Co-Diovan* (including patent

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term extensions). The active ingredient valsartan is also used in the single-pill combination therapies *Exforge* and *Exforge HCT* (high blood pressure). While market exclusivities for *Exforge/Exforge HCT* will remain in the European Union and Japan due to regulatory patent protection, there is a risk that generic manufacturers may circumvent regulatory exclusivity and gain approval of a combination valsartan-amlodipine product in Europe. In the United States, under a license agreement with a generics manufacturer, the product is expected to face generic competition beginning in October 2014.

The patent on *Femara* (cancer) expired in 2011 in the United States and in major European markets, and generic competitors have launched in those markets.

The patent on zoledronic acid, the active ingredient in *Zometa* (cancer), as well as in *Reclast/Aclasta* (osteoporosis), expired in 2012 in a limited number of smaller markets, and will expire in 2013 in the United States and in other major markets. However, certain forms or uses of these products are also covered by additional patents with later expiration dates in certain markets.

The patent on the active ingredient in *Gleevec/Glivec* (cancer) will expire in 2015 in the United States, in 2016 in the major EU countries and 2014 in Japan, in each case including extensions. However, the product is protected by additional patents claiming innovative features of *Gleevec/Glivec*.

In 2013, the impact of generic competition on our net sales is expected to be as much as \$3.5 billion. As we typically have substantially reduced marketing and research and development expenses related to a product in its final year of exclusivity, it is expected that the loss of patent protection will have an impact on our operating income which can be expected to correspond to a significant portion of the product's lost sales. The magnitude of such an impact could depend on a number of factors, including: the time of year at which such exclusivity would be lost; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic competitor products approved, and whether, in the United States, a single competitor is granted an exclusive marketing period; and the geographies in which generic competitor products are approved, including the strength of the market for generic pharmaceutical products in such geographies and the comparative profitability of patented pharmaceutical products in such geographies.

While this wave of patent expiries represents a significant challenge for our Pharmaceuticals and Alcon divisions, it also presents an opportunity for Sandoz, which develops, manufactures, distributes and sells prescription medicines that are not protected by valid and enforceable third-party patents. Global spending on generics is expected to increase from \$242 billion in 2011 to more than \$400 billion by 2016 according to IMS Health, fueled by volume growth in emerging markets and increased demand in developed nations.

#### Heightended Regulatory and Safety Hurdles

The costs associated with bringing a new drug to market have continued to increase as requirements with respect to documentation proving efficacy and safety have become more stringent.

Even after a new drug is approved, there is a risk that safety events could occur in patients, despite our commitment to the highest standards of quality and safety across all of our divisions. Such events could not only harm our reputation and the trust we share with patients who depend on our products, but could also have a negative impact on our results, such as through a reduction in demand, product recalls or withdrawals, or legal proceedings.

Despite this risk, however, we expect that our focus on improving patient outcomes and understanding disease pathways will allow Novartis to continue to bring innovative, effective and safe medicines to market.

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### Risk of Liability and Supply Disruption from Manufacturing Issues

The manufacture of our products is both highly regulated and complex, and may result in a variety of issues that could lead to extended supply disruptions and significant liability. Governmental health authorities around the world, including the FDA, closely regulate the manufacture of our products, and continue to intensify their scrutiny of manufacturers' compliance with their requirements. If we or our third party suppliers fail to comply fully with these requirements, then we could be required to shut down our production facilities or production lines. In this event, we could experience product shortages, or be unable to supply products to patients for an extended period of time, and such shortages or supply failures have led to, and could continue to lead to, significant losses of sales revenue and to potential third party litigation. Health authorities could also impose significant penalties on us.

Like our competitors, we have faced, and in some cases continue to face, significant manufacturing issues. For example, in 2012, we continued to progress quality remediation programs at three of Sandoz's North American manufacturing facilities (following an FDA warning letter in 2011) and at Consumer Health's manufacturing facility in Lincoln, Nebraska, United States, where we suspended operations and shipments at the end of 2011. Although we have made significant progress in 2012 at these sites, as a result of the manufacturing issues, we have suffered and may continue to suffer significant losses in sales and market share. In addition, we have been required to expend considerable resources on the remediation of these sites.

In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For example, a significant portion of the Group's portfolio of products, including products from Pharmaceuticals, Sandoz, and Vaccines and Diagnostics, are "biologic" products, which cannot be manufactured synthetically, but typically must be produced from living plant or animal micro-organisms. In addition, the Group's portfolio includes a number of sterile products, including oncology treatments, which are considered to be technically complex to manufacture and require strict environmental controls. Because the production process for these products is so complex and sensitive, there is a greater chance of production failures and lengthy supply interruptions.

Finally, because our products are intended to promote the health of patients, any manufacturing issues that result in supply disruptions or other production problems could potentially subject us, not only to government penalties, but also to lawsuits or allegations that the public health, or the health of individuals, has been endangered.

## Financial Crisis Increasing Pressures on Drug Prices

Despite hopes that the global economy would recover in 2012, challenges stemming from the 2008 financial crisis continue to weigh on the industry. The economies of Greece, Italy, Portugal and Spain in particular continued to contract under austerity measures, and with budgets under pressure, these governments have taken steps to keep costs down by introducing price reductions and rebates to make medications more affordable. These lower prices affect all of our businesses that rely on reimbursement, including Pharmaceuticals, Alcon, Sandoz, and Vaccines and Diagnostics.

In addition, consumer confidence remains low, and patients around the world are looking for ways to keep healthcare spending to a minimum. In the United States, for example, according to one study, 58% of people reported that they put off or went without necessary treatment in the previous year due to cost, up from 50% in 2011. To combat this trend, Novartis offers coupon programs and incentives for patented products to facilitate access to the most effective treatments at an affordable price. In Brazil, for example, our patient program "Vale mas Saude" provides value-added solutions for the treatment of several chronic conditions (such as hypertension, diabetes, chronic obstructive pulmonary disease, asthma, and neurological disorders) to almost 3 million patients and over 50,000 participating physicians. Educational support and progressive discounts mean more Brazilian patients have access to treatment. In addition,

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patient compliance to treatment has more than doubled in Brazil, along with increased visits to pharmacies.

#### Potential Liability Arising from Legal Proceedings

In recent years, there has been a trend of increasing government investigations and litigations against companies operating in the industries of which we are a part, both in the United States and in an increasing number of countries around the world. We are obligated to comply with the laws of the approximately 140 countries in which we operate, covering an extremely wide range of activities. To that end, we have a significant global compliance with law program in place. Nonetheless, despite our efforts, any failure to comply with the law could lead to substantial liabilities that may not be covered by insurance, and could affect our business and reputation.

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 product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, sales and marketing practices, health and safety issues, environmental remediation, taxation, 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 corruption, marketing practices, insider trading, antitrust, trade restrictions, embargo legislation and data privacy. Responding to such investigations is costly, and requires an increasing amount of our management's time and attention. In addition, such investigations may affect our reputation and create a risk of potential exclusion from government reimbursement programs in the United States and other countries. These factors have contributed to recent decisions by us and other companies in our industry, when deemed in the companies' 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 penalties of up to treble damages. In addition, settlements of healthcare fraud cases often require companies to enter into corporate integrity agreements, which are intended to regulate company behavior for a period of years. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

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.

### **Execution of Focused Diversification Strategy**

To capture opportunities and mitigate risks, Novartis aims to maintain leadership positions in growing segments of the healthcare industry.

### Researching Areas of Growing Unmet Medical Need

Patients are at the center of everything we do, and while many of our competitors have outsourced or partially outsourced their research and development activities, we have continued our efforts to expand and rejuvenate our portfolio through innovation in order to bring new healthcare solutions to market in areas where currently available treatments do not meet patient needs.

Pharmaceuticals and Alcon conduct research through NIBR, which focuses on studying molecular signaling pathways that, when defective, can lead to disease. When drugs pass initial safety and efficacy tests in one disease area, we frequently initiate parallel studies in other indications because illnesses can

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share a common underlying pathway. We also leverage our NIBR R&D investments in Animal Health, as many of the medicines developed for human patients also have applications for pets and farm animals.

Beyond our internal research activities, Novartis also collaborates with partners to develop and commercialize promising treatments that can improve patient outcomes. For example, in 2012, we announced an exclusive, multi-year collaboration with the University of Pennsylvania to research, develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies, a new frontier in oncology research that has the potential to transform the treatment of cancer. Also this year, Alcon entered into a licensing agreement with ThromboGenics to commercialize *Jetrea* (ocriplasmin), the first pharmacological treatment for vitreomacular adhesion (VMA), outside of the United States. Ocriplasmin has been submitted for approval in the EU, and in January 2013 received a positive CHMP opinion. Ocriplasmin received FDA approval in October 2012. There are more than 300,000 VMA patients in Europe alone who could potentially benefit from ocriplasmin. If approved, Alcon plans to introduce ocriplasmin in more than 40 countries worldwide.

In addition, we have a significant pipeline of cardiovascular products in late-stage development, with both RLX030 in development for acute heart failure (from the acquisition of Corthera Inc. in 2010) and LCZ696 in development for hypertension and chronic heart failure. Both RLX030 and LCZ696 have the potential to address large patient populations, as the prevalence of heart failure is increasing. Chronic heart failure currently affects 20 million people worldwide and is projected to grow by 2.3% over the next decade. Of the 2 million people with acute heart failure who are discharged from the hospital each year in the United States and Europe, approximately 50% could be eligible for RLX030, if approved.

We believe that our focus on researching areas of unmet need will allow us to extend our lead in innovation. We continued our strong track record of bringing new medicines and indications to market in 2012, as our Pharmaceuticals Division secured 11 major approvals for new products and indications in the United States and European Union, on top of significant approvals in Alcon and Vaccines and Diagnostics.

#### Focusing on Patient Outcomes

Reflecting our commitment to patients, our strategy has moved from a transactional approach of simply selling pills to a more integrated approach that focuses on improving health outcomes and partnering with customers to deliver more services for patients.

We have developed support programs aimed at improving access and adherence to our treatments, which are expected to improve health outcomes and cut excess costs associated with low levels of adherence. For example, we established a *Gilenya* support program in the United States that provides MS patients with a nurse navigator to help arrange medical tests and improve compliance by following up with patients on a monthly basis. We are also in the process of conducting patient segmentation market research to understand issues around MS treatment adherence, and plan to develop and offer an adherence program through the nurse navigator program later in the year.

Similarly, in Sandoz, we work to bring biopharmaceuticals to patients in need earlier in disease progression, aiming to help prevent the onset of serious or life-threatening complications. For example, in the UK, the introduction of biosimilar filgrastim moved the medication from a second-line to first-line treatment for febrile neutropenia associated with chemotherapy a shift that significantly increased access to this important therapy for thousands of cancer patients.

#### Tailoring Commercial Models Around Customer Needs

In today's healthcare landscape, in which access to physicians is becoming increasingly restricted for sales representatives, Novartis collaborates with key customer segments in an effort to provide doctors and patients with the information and support they need. This partnership not only improves our relationships with important customers, but also may enable doctors to provide better care to patients.

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Our "Key Account Management" approach, for example, allows us to identify opportunities to collaborate with customers to help them support patients and providers. In Taiwan, we instituted a patient education program along with one of our customers that helped to reduce stroke patient re-hospitalization rates from 23% to 15% while ensuring access to Novartis medications. We implemented a global franchise model within Alcon to encourage functional excellence, cross-functional collaboration and accelerated decision-making across R&D, commercial and manufacturing, enhancing innovation and speed-to-market of new products.

For doctors, our support comes in the form of education, raising awareness of the latest advances in our understanding of disease pathways and treatment options so they can provide the highest quality of care to patients. For example, in Sandoz, we are growing our medical affairs outreach to educate physicians about biosimilars products and assist them in understanding the value that these treatment options can provide. Novartis is also committed to working with payors to enable eligible patients to benefit from access to our industry-leading portfolio and, to that end, has over 150 individual patient access programs around the world.

#### **Engaging Patients in Their Care**

In a recent survey, 50% of Americans said that texts, emails or smartphone applications with tips, reminders and encouragement could have helped them avoid a health problem in the past. To improve patient outcomes, Novartis is working to leverage the channels that patients use on a day-to-day basis to engage them in their own care. For example, in the UK, Sandoz launched a novel disease education tool that uses augmented reality to educate young children about growth hormone deficiencies.

Additionally, while patients could obtain better health outcomes by participating in clinical trials for new innovative treatments, very few of them do: only 2% of Americans get involved with clinical research each year and less than 4% of United States physicians ever participate, according to the Center for Information and Study on Clinical Research Participation. Novartis, in partnership with electronic health record (EHR) management companies, is piloting a process in which physicians are notified by the EHR management company about relevant ongoing clinical trials when they enter data into the EHR. By engaging patients at their point of care, we provide them with the information they need to make well-informed decisions about their health.

Alcon, too, has a long history of empowering patients by working with eye care professionals and policymakers to raise awareness about eye diseases and treatment options. For example, in Europe, Alcon works with policymakers to provide cataract patients with a choice between cataract surgery with a conventional intraocular lens (which is fully reimbursed), and cataract surgery with an advanced technology intraocular lens, which corrects refractive errors, such as presbyopia and astigmatism, while removing their cataract (which is available with a co-payment).

### Enhancing Access to Healthcare

Access to healthcare is a global challenge, and bridging the access gap is a goal Novartis shares with governments, international agencies like the WHO, foundations and nongovernmental organizations.

At Novartis, enhancing access begins with medical research, continues with product donations and new business models, and is supported by action to strengthen healthcare in both developing and advanced economies. In 2012, our access-to-healthcare contributions and programs were valued at more than \$2.0 billion, providing medicine to approximately 100 million patients and health education, infrastructure development and other programs to another 7.2 million people worldwide. Millions more purchased high-quality, low-cost generics from our Sandoz Division.

However, no single company no matter how committed to patients can bridge the access gap alone. Barriers to access can be overcome only with effective and coordinated action by all parties involved.

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In 2012, Novartis extended its collaboration with the WHO and other organizations to eliminate leprosy. As part of a donation valued at more than \$20 million, Novartis will continue to provide free multidrug therapy medicines to treat an estimated 850,000 people with leprosy through 2020. Similarly, Sandoz is working with the Zambian government to increase access to high-quality, affordable medicines across Africa by supporting small, independent health shops, the primary healthcare providers in rural areas. This support helps efforts to provide a consistent, reliable and safe supply of drugs for Zambia's patients, which in turn helps the country reach several of its UN Millennium Development Goals by 2015. In addition, Alcon supports more than 800 medical missions and numerous partnerships with non-profit organizations each year to bring eye care to places in which services and treatments are not yet available, train local physicians to perform state-of-the-art surgery and provide sustainable eye care.

In addition, following the success of its Arogya Parivar ("healthy family") program in India, Novartis launched Familia Nawiri in Kenya and Cung Song Khoe in Vietnam in 2012. These localized social business models aim to expand access to quality healthcare for people living at the bottom of the pyramid without consistent access to healthcare or health education.

#### FACTORS AFFECTING COMPARABILITY OF YEAR-ON-YEAR RESULTS OF OPERATIONS

#### **Recent Acquisitions and Divestments**

The comparability of the year-on-year results of our operations for the total Group can be significantly affected by acquisitions and divestments. For more detail how transactions of significance have affected our results, see "Significant Transactions" below.

#### **Significant Transactions**

#### Acquisitions in 2012

Sandoz Acquisition of Fougera Pharmaceuticals, Inc.

On July 20, 2012, Sandoz completed the acquisition of 100% of Fougera Pharmaceuticals, Inc. a specialty dermatology generics company based in Melville, New York, for \$1.5 billion in cash. The acquisition of Fougera Pharmaceuticals, Inc. creates another strong global growth platform for Sandoz. Fougera has strong dermatology development and manufacturing expertise and employs approximately 700 people.

The final purchase price allocation resulted in net identified assets of \$0.6 billion (excluding acquired cash) and goodwill of \$0.9 billion. Results of operations since the acquisition date were not material.

### Acquisitions 2011

Alcon majority control in 2010; full ownership and merger in 2011

On August 25, 2010, Novartis completed the acquisition of a further 52% interest in Alcon, Inc. (Alcon) following on from the January 4, 2010 announcement that Novartis had exercised its call option to acquire Nestlé's remaining 52% Alcon interest for approximately \$28.3 billion or \$180 per share. The overall purchase price of \$38.7 billion included certain adjustments for Alcon dividends and interest due. This increased our interest in Alcon to a 77% controlling interest as Novartis had already acquired an initial 25% Alcon interest from Nestlé for \$10.4 billion or \$143 per share in July 2008.

On December 14, 2010, Novartis entered into a definitive agreement to merge Alcon into Novartis in consideration for Novartis shares and a Contingent Value Amount. The acquisition of the remaining outstanding non-controlling interests in Alcon were separate transactions following the previous acquisition of majority ownership in Alcon by Novartis in 2010.

On April 8, 2011 a Novartis Extraordinary General Meeting approved the merger of Alcon, Inc. with Novartis AG leading to the creation of the Alcon Division which became the fifth reported segment in

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Novartis' strategically diversified healthcare portfolio. The Extraordinary General Meeting also authorized the issuance of 108 million new shares. Alcon shareholders received 2.9228 Novartis shares (which included a dividend adjustment) and \$8.20 in cash for each share of Alcon, resulting in a total consideration of \$168.00 per share.

For business combinations achieved in stages, IFRS requires that any previously held interest of an acquirer in an acquiree is adjusted to its fair value through the consolidated income statement as of the acquisition date. The agreement that Novartis entered into with Nestlé in 2008 specified an average price of up to \$168 per share for all of the approximately 77% interest in Alcon held by Nestlé, including \$143 per share for the initial 25% interest acquired by Novartis in 2008, and a maximum of \$181 per share for the remaining 52%, including a premium for the change of majority ownership.

Novartis reassessed the fair value of the initial 25% non-controlling interest in Alcon it acquired from Nestlé in 2008. In 2010, Novartis recognized a revaluation gain of \$378 million on its initial 25% equity-method investment in Alcon upon acquiring a 52% controlling interest in the second-stage purchase from Nestlé on August 25, 2010. This gain was based on Novartis concluding that the fair value of that interest had a corresponding per-share value of \$139. On this date the quoted market price of Alcon on the NYSE was \$160. Novartis measured this revaluation gain based on the estimated current fair value of its investment in Alcon, with the assistance of outside specialist investment bank advisors. This valuation demonstrated that, as at August 25, 2010, the quoted price for Alcon was affected by an anticipated premium on Novartis' eventual purchase of the 23% not owned at that time. Novartis concluded that this "premium" should not be included in the valuation of the previously held equity interest.

This gain was reduced by \$43 million of accumulated losses recorded in the consolidated statement of comprehensive income of Novartis since the July 2008 acquisition date of the initial interest. These accumulated losses were recorded under the equity accounting method, which requires such accumulated losses to be recycled into the consolidated income statement at the time of acquiring majority ownership. The net amount of \$335 million was recorded as a gain under "Income from Associated Companies".

At December 31, 2010 Novartis recorded the outstanding non-controlling interests in Alcon at their proportionate share of identifiable net assets which amounted to \$6.3 billion. After the acquisition of majority ownership in Alcon, Inc. on August 25, 2010, Alcon contributed in 2010 net sales \$2.4 billion and operating income of \$323 million to the 2010 consolidated income statement.

During 2011, prior to the merger on April 8, 2011, 4.8% of the non-controlling interests in Alcon, Inc. were acquired for \$2.4 billion. Completion of the acquisition of the outstanding 18.6% of Alcon Inc. on April 8, 2011 and subsequent merger, resulted in the issuance of Novartis shares with a fair value of \$9.2 billion and a payment in cash of \$0.5 billion to the Alcon, Inc. shareholders.

The final purchase price allocation was completed in 2011 and resulted in a fair value of net identifiable assets of \$27.0 billion and goodwill of \$18.0 billion. The excess of the value exchanged for the non-controlling interests in Alcon Inc, in 2011 over its recorded value together with merger related transaction costs resulted in a reduction in the Novartis consolidated equity of \$5.7 billion.

For more detail on accounting for these transactions, see "Item 18. Financial Statements" note 1, 2 and 24".

Pharmaceuticals Acquisition of Genoptix, Inc.

On March 7, 2011 Novartis completed the acquisition of 100% of Genoptix, Inc., a specialized laboratory providing personalized diagnostic services to United States community-based hematologists and oncologists for \$458 million in cash. Genoptix employed approximately 500 people. The final purchase price allocation resulted in net identified assets of \$237 million and goodwill of \$221 million. Results of operations since the acquisition date in 2011 were not material.

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#### Acquisitions in 2010 (additional to the Alcon transaction described above)

Pharmaceuticals Acquisition of Corthera

On February 3, 2010 Novartis completed the 100% acquisition (announced on December 23, 2009) of the privately held US-based Corthera Inc., gaining worldwide rights to relaxin for the treatment of acute decompensated heart failure and assumed full responsibility for development and commercialization for a total purchase consideration of \$327 million. This amount consists of an initial cash payment of \$120 million and \$207 million of deferred contingent consideration. The deferred contingent consideration initially recognized represented the net present value of the additional milestone payments due to Corthera's previous shareholders which they are eligible to receive contingent upon the achievement of specified development and commercialization milestones. The final purchase price allocation resulted in net identified assets of \$309 million and goodwill of \$18 million. Results of operations since the acquisition date were not material.

Sandoz Acquisition of Oriel Therapeutics

On June 1, Sandoz completed the 100% acquisition of the privately held US-based Oriel Therapeutics Inc., to broaden its portfolio of projects in the field of respiratory drugs for a total purchase consideration of \$332 million. This amount consists of an initial cash payment of \$74 million and \$258 million of deferred contingent consideration. Oriel's previous shareholders are eligible to receive milestone payments, which are contingent upon the company achieving future development steps, regulatory approvals and market launches, and sales royalties. The total \$258 million of deferred contingent consideration initially recognized represented the net present value of expected milestone and royalty payments. The final purchase price allocation, including the valuation of the contingent payment elements of the purchase price, resulted in net identified assets of \$281 million and goodwill of \$51 million. Results of operations since the acquisition date were not material.

#### Other Significant Transactions in 2010

Pharmaceuticals Divestment of Enablex®

On October 18, 2010 Novartis finalized the sale of the US rights for Enablex® (darifenacin) to Warner Chilcott Plc for \$400 million and recongized a gain of \$392 million.

Corporate Change of pension plan in Switzerland

On April 23, 2010 the Board of Trustees of the Novartis Swiss Pension Fund agreed to amend the conditions and insured benefits of the current Swiss pension plan with effect from January 1, 2011. These amendments do not have an impact on existing pensions in payment or on plan members born before January 1, 1956. Under the previous rules, benefits from the plan are primarily linked to the level of salary in the years prior to retirement while under the new rules benefits are also partially linked to the level of contributions made by the members during their active service period up to their retirement. This has led to changes in the amounts that need to be included in the Group's consolidated financial statements prepared using IFRS in respect of the Swiss Pension Fund.

As part of this change, Novartis, supported by the Swiss Pension Fund, will make transitional payments, which vary according to the member's age and years of service. As a result, it is estimated that additional payments will be made over a ten-year period of up to approximately \$481 million (CHF 453 million) depending on whether or not all current members affected by the change remain in the plan over this ten-year period.

The accounting consequence of this change in the Swiss pension plan rules results in the Group's consolidated financial statements prepared under IFRS reflecting a net pre-tax curtailment gain of \$265 million (CHF 283 million) in 2010. This calculation only takes into account the discounted value of transition payments of \$202 million (CHF 219 million) attributed to already completed years of service of the affected plan members as calculated in accordance with IFRS requirements. It does not take into account any amount for transitional payments related to their future years of service.

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#### NON-IFRS MEASURES AS DEFINED BY NOVARTIS

The following non-IFRS metrics are used by Novartis when measuring performance, especially when measuring current year results against prior periods: core results, constant currencies, free cash flow and net debt.

Despite the use of these measures by management in setting goals and measuring the Group's performance, these are non-IFRS measures that have no standardized meaning prescribed by IFRS. As a result, such measures have limits in their usefulness to investors.

Because of their non-standardized definitions, the non-IFRS measures (unlike IFRS measures) may not be comparable to the calculation of similar measures of other companies. These measures are presented solely to permit investors to more fully understand how the Group's management assesses underlying performance. These measures are not, and should not be viewed as, a substitute for IFRS measures.

As an internal measure of Group performance, these measures have limitations, and the performance management process is not solely restricted to these metrics.

#### **Core Results**

The Group's core results including core operating income, core net income and core earnings per share exclude the amortization of intangible assets, impairment charges, expenses relating to the integration of acquisitions as well as other items that are, or are expected to accumulate within the year to be, over a \$25 million threshold that management deems exceptional.

Novartis believes that investor understanding of the Group's performance is enhanced by disclosing core measures of performance because, since they exclude these exceptional items which can vary significantly from year to year, the core measures enable better comparison across years. For this same reason, Novartis uses these core measures in addition to IFRS and other measures as important factors in assessing the Group's performance.

The following are examples of how these core measures are utilized:

In addition to monthly reports containing financial information prepared under IFRS, senior management receives a monthly analysis incorporating these core measures.

Annual budgets are prepared for both IFRS and core measures.

### **Constant Currencies**

Changes in the relative values of non-US currencies to the US dollar can affect the Group's financial results and financial position. To provide additional information that may be useful to investors, including changes in sales volume, we present information about our net sales and various values relating to operating and net income that are adjusted for such foreign currency effects.

Constant currency calculations have the goal of eliminating two exchange rate effects so that an estimate can be made of underlying changes in the consolidated income statement excluding the impact of fluctuations in exchange rates:

the impact of translating the income statements of consolidated entities from their non-dollar functional currencies to dollars; and

the impact of exchange rate movements on the major transactions of consolidated entities performed in currencies other than their functional currency.

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We calculate constant currency measures by translating the current year's foreign currency values of the net sales and earnings into dollars using the average exchange rates from the prior year and comparing them to the prior year values in dollars.

We use these constant currency measures in evaluating the Group's performance, since they may assist us in evaluating our ongoing performance from year to year. However, in performing our evaluation, we also consider equivalent measures of performance which do not take into account changes in the relative value of currencies.

#### Free Cash Flow

Novartis defines free cash flow as cash flow from operating activities excluding cash flow associated with the purchase or sale of property, plant & equipment, intangible, other non-current and financial assets. Cash flows in connection with the acquisition or divestment of subsidiaries, associated companies and non-controlling interests are also excluded from free cash flow.

Free cash flow is presented as additional information because Novartis considers it to be a useful indicator of the Group's ability to operate without relying on additional borrowing or the use of existing cash. Free cash flow is a measure of the net cash generated that is available for dividend payments, debt repayment and investment in strategic opportunities. The Group uses free cash flow as a performance measure when making internal comparisons of the results of divisions. Free cash flow constitutes a non-IFRS financial measure, which means that it should not be interpreted as a measure determined under IFRS. Free cash flow is not intended to be a substitute measure for cash flow from operating activities (as determined under IFRS).

#### Net Debt

Novartis defines net debt as our cash and cash equivalents, current investments and derivative financial instruments less interest-bearing loans and borrowings.

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The following tables reconcile IFRS results to core results:

#### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS GROUP

2012	IFRS results	Amortizatio of intangible assets <sup>(1)</sup>				Core results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	38,805	2,786	174	39	43	41,847
Operating income	11,511	2,876	356	330	87	15,160
Income before taxes	11,243	3,045	356	364	87	15,095
Taxes	(1,625)					$(2,284)^{(5)}$
Net income	9,618					12,811
Basic earnings per share (\$) <sup>(6)</sup>	3.93					5.25
The following are adjustments to arrive at Core Gross Profit						
Other revenues	888				(56)	832
Cost of goods sold	(18,756)	2,786	174	39	99	(15,658)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(14,353)			1		(14,352)
Research & Development	(9,332)		109		20	(9,116)
General & Administration	(2,937)				14	(2,923)
Other income	1,187		(1)		(373)	813
Other expense	(1,859)	3	74	290	383	(1,109)
The following are adjustments to arrive at Core Income before taxes Income from associated companies	552	169	)	34		755

(3)

(2)

(1)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; Other expense includes amortization of intangible assets; Income from associated companies includes the recurring amortization of the purchase price allocation related to intangible assets included in the Novartis equity-method accounting for Roche of \$153 million and \$16 million for the Novartis share of the estimated Roche core items.

Impairments: Cost of goods sold, Research & Development, Other income, and Other expense include principally impairments of intangible assets and property, plant & equipment; Other expense also includes impairments of financial assets.

Acquisition or divestment related items, restructuring and integration charges: Cost of goods sold includes acquisition related inventory step-up adjustments; Marketing & Sales and Other expense relate to Alcon and Fougera integration costs; Income from associated companies includes a \$16 million revaluation gain on the initial interest in an acquired company and the Novartis share of \$50 million restructuring charge related to Roche.

(4)

Other exceptional items: Other revenues include an income of \$56 million related to an intellectual property settlement and license agreement; Cost of goods sold, Research & Development, Other income, and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold also includes

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an additional charge of \$22 million for product recalls related to a US production plant; Research & Development also includes a net \$18 million increase of contingent consideration liabilities related to business combinations; General & Administration includes exceptional IT-related costs; Other income includes a provision reduction of \$137 million mainly related to *Tekturna/Rasilez* inventories, a product divestment gain of \$93 million, a reversal of prior year restructuring charges of \$76 million, and a gain on divestment related to the Novartis Venture Funds of \$51 million; Other expense includes principally a restructuring charge of \$149 million related to the US business, and charges for transforming IT and finance processes of \$117 million.

(5)

Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not the case for items arising from criminal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of \$3.9 billion to arrive at the core results before tax amounts to \$659 million. This results in the average tax rate on the adjustments being 17.1%.

(6)

Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

				Acquisition or divestment related items,		
	1	Amortizatio	n r	estructuring		
		of		and		~
2011	IFRS results	intangible assets <sup>(1)</sup>	Impairments <sup>(2)</sup>	_	Exceptional items <sup>(4)</sup>	Core results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	40,392	2,918	278	5	246	43,839
Operating income	10,998	3,028	1,224	148	511	15,909
Income before taxes	10,773	3,238	1,224	148	552	15,935
Taxes	(1,528)					$(2,445)^{(5)}$
Net income	9,245					13,490
Basic earnings per share (\$) <sup>(6)</sup>	3.83					5.57
The following are adjustments to arrive at Core Gross Profit						
Net sales	58,566				117	58,683
Cost of goods sold	(18,983)	2,918	278	5	129	(15,653)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(15,079)				2	(15,077)
Research & Development	(9,583)				(90)	(9,239)
General & Administration Other income	(2,970) 1,354	13		(102)	(806)	(2,957) 443
Other expense	(3,116)	4	(3) 608	245	1,159	(1,100)
The following are adjustments to arrive at Core Income before taxes				273		
Income from associated companies	528	210			41	779

(1)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets; Other expense includes amortization of intangible assets; Income from associated companies includes

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(4)

the recurring amortization of the purchase price allocation related to intangible assets included in the Novartis equity-method accounting for Roche of \$162 million and \$48 million for the Novartis share of the estimated Roche core items.

- Impairments: Cost of goods sold includes impairment charges related to *Tekturna/Rasilez*, Consumer Health in the US, and other intangible assets; Research & Development includes impairment charges principally for PTK796, AGO178 (agomelatine), PRT128, SMC021 and In Process Research & Development; Other income includes an impairment reversal; Other expense includes impairments of \$314 million related to *Tekturna/Rasilez*, \$47 million related to SMC021, \$17 million related to the Group-wide rationalization of manufacturing sites, and amounts for financial assets.
- Acquisition-related divestment gains, restructuring and integration charges: Cost of goods sold includes an acquisition related inventory step-up adjustment; Other income includes a gain from product sales required by regulators to approve the Alcon merger; Other expense relates primarily to Alcon integration costs.
- Exceptional items: Net sales to third parties includes a returns provision related to *Tekturna/Rasilez* and a recall provision related to over-the-counter products; Cost of goods sold and Marketing & Sales include charges related to Consumer Health in the US; Cost of goods sold, Research & Development, Other income, and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold and Other expense include Swiss restructuring charges of \$254 million; Research & Development includes a reduction to a contingent consideration liability related to a business combination of \$106 million in Sandoz; Other income and expense include a net \$183 million gain from the Jump litigation settlement and a \$100 million settlement gain, a \$85 million insurance settlement gain, product divestment gains of \$378 million, charges of \$284 million related to legal settlements, \$161 million for IT and finance restructuring projects, an amount of \$295 million related to *Tekturna/Rasilez*, an amount of \$13 million related to SMC021, and other restructuring charges; Income from associated companies reflects a charge of \$41 million for the Novartis share of Roche's restructuring.
- Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that is applicable to the item in the jurisdiction where the adjustment arises. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not the case for items arising from criminal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of \$5.2 billion to arrive at the core results before tax amounts to \$917 million. This results in the average tax rate on the adjustments being 17.8%.
- (6) Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

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(1)

(2)

(3)

2010	IFRS results	Amortizatio of intangible assets <sup>(1)</sup>	n r	Acquisition or divestment related items, estructuring and integration 1 charges (3)		Core results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	37,073	1,061	(90)	471	2	38,517
Operating income	11,526	1,135	981	600	(236)	14,006
Income before taxes	11,702	1,560	981	280	(104)	14,419
Taxes <sup>(5)</sup>	(1,733)					(2,390)
Net income	9,969					12,029
Basic earnings per share (\$) <sup>(6)</sup>	4.28					5.15
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(14,488)	1,061	(90)	471	2	(13,044)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(13,316)	1				(13,315)
Research & Development	(9,070)	69	903		18	(8,080)
General & Administration	(2,481)	4				(2,477)
Other income	1,234		(10)		(739)	485
Other expense	(1,914)		178	129	483	(1,124)
The following are adjustments to arrive at Core Income before taxes						
Income from associated companies	804	425		(320)	132	1,041

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Marketing & Sales includes the recurring amortization of intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets; Income from associated companies includes the recurring amortization of the purchase price allocation related to intangible assets, primarily for the Roche and Alcon investments.

Impairments: Cost of goods sold includes impairment charges for acquired rights to in-market products and production-related impairment charges, including an additional reversal of \$100 million in Pharmaceuticals for an impairment charge taken in 2007 for *Famvir*; Research & Development includes write-offs related to in-process Research & Development, mainly charges totalling \$856 million for the discontinuation of *Mycograb*, albinterferon alfa-2b, PTZ601 and ASA404 development projects; Other income includes the reversal of impairments, primarily for property, plant & equipment; Other expense includes impairments, primarily for financial assets, thereof \$45 million in Pharmaceuticals, \$98 million in Vaccines and Diagnostics and \$20 million in Corporate as well as \$14 million in Vaccines and Diagnostics for property, plant & equipment.

Acquisition-related restructuring and integration items: Cost of goods sold includes mainly charges of \$467 million related to the required inventory step-up to estimated fair value in Alcon; Other expense includes charges in Corporate of \$99 million related to the acquisition of Alcon and \$30 million recorded in Alcon related to the change of majority ownership of Alcon; Income from associated companies includes a \$378 million revaluation gain

on the initial 25% interest in Alcon, a \$43 million charge for the recycling of losses accumulated in comprehensive income related to Alcon since its inclusion as an associated company in 2008, and a \$15 million charge for the change of majority ownership.

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(6)

(3)

Exceptional items: Cost of goods sold includes charges related to inventory write-off in Vaccines and Diagnostics due to a restructuring program; Research & Development includes an expense of \$18 million for termination of a co-development contract in Sandoz; Other income includes a divestment gain of \$392 million for the divestment of *Enablex* in Pharmaceuticals, proceeds of \$42 million from a legal settlement in Pharmaceuticals with Teva regarding *Famvir*, a divestment gain of \$33 million for *Tofranil* in Pharmaceuticals and a Swiss pension curtailment gain of \$265 million in Corporate; Other expense includes mainly a \$152.5 million provision for a gender discrimination case in the US in Pharmaceuticals, charges of \$203 million for restructuring programs in Pharmaceuticals, Vaccines and Diagnostics, and Sandoz, a \$25.5 million provision in connection with a government investigation in the US in Pharmaceuticals, \$45 million for a legal settlement in Vaccines and Diagnostics, and a \$38 million charge for a legal settlement in Sandoz; Income from associated companies reflects an additional charge of \$43 million for the Novartis share of Roche's restructuring charges for Genentech taken in the second half of 2009 but recorded by Novartis in 2010 as well as an estimated charge of \$89 million for the Novartis share of Roche's restructuring that was recently announced.

Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that is applicable to the item in the jurisdiction where the adjustment arises. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not the case for items arising from criminal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of \$2.7 billion to arrive at the core results before tax amounts to \$657 million. This results in the average tax rate on the adjustments being 24.2%.

Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

#### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS PHARMACEUTICALS

2012	IFRS results	Amortization of intangible assets <sup>(1)</sup>	Impairments <sup>(2)</sup>	Other exceptional items <sup>(3)</sup>	Core results
	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	26,323	270	120	54	26,767
Operating income	9,598	322	238	55	10,213
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(6,578)	270	120	54	(6,134)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(6,918)	52	91	78	(6,697)
Other income	577		(1)	(303)	273
Other expense	(755)		28	226	(501)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Cost of goods sold includes impairments related to marketed products; Research & Development includes principally impairment charges related to In Process Research & Development; Other income includes reversal of impairment of property, plant & equipment; Other expense includes impairments of property, plant & equipment and financial assets.

Other exceptional items: Cost of goods sold, Research & Development, Other income, and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Research & Development includes principally an increase of a contingent consideration liability related to a business combination; Other income

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includes a provision reduction of \$137 million mainly related to *Tekturna/Rasilez* inventories, a product divestment gain of \$93 million, and reversal of prior year restructuring charges of \$70 million; Other expense includes a restructuring charge of \$149 million related to the US business, an additional legal settlement provision of \$19 million and an additional provision of \$19 million related to *Tekturna/Rasilez* clinical studies, and a restructuring charge of \$42 million related to the European and Asian business.

				Acquisition or		
				divestment		
				related		
				items,		
	A	Amortization of	n ı	estructuring	5	
	IFRS	oı intangible		and	Exceptional	Core
2011	results		Impairments <sup>(2)</sup>		items <sup>(4)</sup>	results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	26,632	369	249		115	27,365
Operating income	8,296	423	985	(81)	417	10,040
The following are adjustments to arrive at Core						
Gross Profit						
Net sales to third parties	32,508				44	32,552
Cost of goods sold	(6,573)	369	249		71	(5,884)
The following are adjustments to arrive at Core						
Operating Income						
Research & Development	(7,232)	54	303		15	(6,860)
Other income	697		(3)	(81)		177
Other expense	(1,825)		436		723	(666)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Cost of goods sold includes impairments primarily related to *Tekturna/Rasilez*; Research & Development includes impairment charges principally for PTK796, AGO178 (agomelatine), PRT128 and SMC021; Other income includes an impairment reversal; Other expense includes impairments of \$314 million related to *Tekturna/Rasilez* and \$47 million related to SMC021, for financial assets, and related to the Group-wide rationalization of manufacturing sites.

Acquisition-related divestment gains, restructuring and integration charges: Other income includes a gain from a product sale required by regulators to approve the Alcon merger.

Exceptional items: Net sales to third parties includes a returns provision related to *Tekturna/Rasilez*; Cost of goods sold, Research & Development and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold and Other expense include Swiss restructuring charges totalling \$249 million; Other income includes a net product divestment gain of \$334 million and a settlement income of \$100 million and items related to the Group-wide rationalization of manufacturing sites; Other expense also includes an amount for a legal settlement of \$80 million, an amount of \$295 million related to *Tekturna/Rasilez*, an amount of \$13 million related to SMC021, and other restructuring charges.

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2010 <sup>(1)</sup>	IFRS results \$ m	Amortization of intangible assets <sup>(2)</sup> \$ m	Impairments <sup>(3)</sup>	Exceptional items <sup>(4)</sup>	Core results \$ m
Gross profit	25,613	421	(100)		25,934
Operating income	8,471	457	833	(175)	9,586
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,272)	421	(100)		(4,951)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(7,276)	36	896		(6,344)
Other income	687	30	(8)	(474)	205
			` ′	` /	
Other expense	(971)		45	299	(627)

Exceptional items: Other income includes a divestment gain of \$392 million for the divestment of *Enablex*, proceeds of \$42 million from a legal settlement with Teva regarding *Famvir* and a divestment gain of \$33 million for *Tofranil*; Other expense includes a \$152.5 million provision for a gender discrimination case in the US, a \$111 million charge for restructuring in the US as well as a \$25.5 million provision in connection with a government investigation in the US.

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<sup>(1)</sup>Restated to reflect new divisional segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Cost of goods sold includes impairment charges for acquired rights to in-market products and other production-related impairment charges, including an additional reversal of \$100 million for an impairment charge taken in 2007 for Famvir; Research & Development includes write-offs related to in-process Research & Development, mainly a total of \$704 million charge for the discontinuation of Mycograb (\$356 million), albinterferon alfa-2b (\$228 million) and ASA404 (\$120 million) development projects and a net pre-tax impairment charge of \$152 million (\$250 million related to the value of the intangible asset offset by a release of a \$98 million liability related to the estimated value of a contingent milestone consideration) for termination of the PTZ601 development project; Other income includes the reversal of impairments, primarily for property, plant & equipment; Other expense includes impairments, primarily for financial assets.

(1)

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### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS ALCON RESTATED

	2012	IFRS results	Amortizatio of intangible assets <sup>(1)</sup>	n i			Core results
\$m \$m \$m \$m \$m		\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit 5,716 1,906 1 16 7,639	Gross profit	5,716	1,906	1		16	7,639
Operating income 1,465 1,915 17 264 37 3,698	Operating income	1,465	1,915	17	264	37	3,698
The following are adjustments to arrive at Core	· · · · · · · · · · · · · · · · · · ·						
Gross Profit							
Cost of goods sold (4,618) 1,906 1 16 (2,695)	Cost of goods sold	(4,618)	1,906	1		16	(2,695)
The following are adjustments to arrive at Core Operating Income							
Research & Development (975) 9 16 (950)	Research & Development	(975)	9	16			(950)
General & Administration (510) 14 (496)	General & Administration	(510)				14	(496)
Other income 49 (1) 48	Other income	49				(1)	48
Other expense (353) 264 8 (81)	Other expense	(353)			264	8	(81)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2)
Impairments: Cost of goods sold includes impairments of intangible assets; Research & Development includes impairment charges related to In Process Research & Development.

Acquisition or divestment related items, restructuring and integration charges: Other expense relates to Alcon integration costs.

Other exceptional items: Cost of goods sold, Other income, and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; General & Administration includes exceptional IT costs.

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				Acquisition		
				or		
				divestment		
				related		
				items,		
	A	Amortization	r	estructuring	g	
		of		and		
	<b>IFRS</b>	intangible			Exceptional	Core
2011	results	assets(1) In	npairments <sup>(2)</sup>	charges <sup>(3)</sup>	items <sup>(4)</sup>	results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	5,457	1,912			20	7,389
Operating income	1,472	1,928	29	212	(149)	3,492
The following are adjustments to arrive at Core						
Gross Profit						
Cost of goods sold	(4,566)	1,912			20	(2,634)
The following are adjustments to arrive at Core						
Operating Income						
Research & Development	(892)	3	20			(869)
General & Administration	(509)	13				(496)
Other income	262			(21)	(229)	12
Other expense	(309)		9	233	60	(7)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets.

Impairments: Research & Development includes an In Process Research & Development impairment charge; Other expense includes impairment charges primarily related to the Group-wide rationalization of manufacturing sites.

Acquisition-related divestment gains, restructuring and integration charges: Other income includes a gain from a product sale required by regulators to approve the Alcon merger; Other expense includes a loss from an Alcon merger-related divestment and Alcon integration costs.

Exceptional items: Cost of goods sold and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold includes a reduction to a contingent consideration provision related to a business combination; Other income and expense includes a net \$183 million gain from the Jump litigation settlement.

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$2010^{(1),(2)}$	IFRS results	Amortization of intangible assets <sup>(3)</sup>	Acquisition or divestment related items, restructuring and integration charges <sup>(4)</sup>	Core results
	\$ m	\$ m	\$ m	\$ m
Gross profit	2,734	60	459	3,253
Operating income	796	65	489	1,350
The following are adjustments to arrive at Core Gross Profit				
Cost of goods sold	(1,760)	60	459	(1,241)
The following are adjustments to arrive at Core Operating Income				
Research & Development	(352)	1		(351)
General & Administration	(255)	4		(251)
Other expense	(39)		30	(9)

<sup>(1)</sup>Restated to reflect new divisional segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

Consolidated results of Alcon, Inc., only included for the period from acquiring control on August 25, 2010 to December 31, 2010. Activities transferred from Pharmaceuticals and CIBA Vision transferred from Consumer Health included for the full year.

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets.

<sup>(4)</sup> Acquisition-related restructuring and integration items: Cost of goods sold relates to the required inventory step-up to estimated fair value; Other expense includes charges of \$30 million related to the change of majority ownership.

(3)

#### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS SANDOZ

			Acc	quisition		
				or		
			div	estment		
			r	elated		
			j	items,		
	A	mortization		ructuring		
		of		and	Other	
	IFRS	intangible	inte	egration ex		Core
2012	results		pairments <sup>(2)</sup> ch		items <sup>(4)</sup>	results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	3,867	356	46	36	4	4,309
-						
Operating income	1,091	364	46	62	(60)	1,503
The following are adjustments to arrive at						
Core Gross Profit						
Cost of goods sold	(5,126)	356	46	36	4	(4,684)
The following are adjustments to arrive at						
Core Operating Income						
Marketing & Sales	(1,561)			1		(1,560)
Research & Development	(695)	8	(3)		(59)	(749)
Other income	74				(10)	64
Other expense	(244)		3	25	5	(211)
*	` /					` /

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Cost of goods sold includes impairments of intangible assets; Research & Development includes principally a reversal of impairment charges related to In Process Research & Development; Other expense includes impairments of property, plant & equipment.

Acquisition or divestment related items, restructuring and integration charges: Cost of goods sold includes Fougera related inventory step-up adjustment; Marketing & Sales and Other expense relates to Fougera integration costs.

Other exceptional items: Cost of goods sold and Other income include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Research & Development includes principally a decrease of a contingent consideration liability related to a business combination; Other income also includes a restructuring provision release; Other expense includes exceptional remediation charges.

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2011	IFRS results \$ m	Amortization of intangible assets <sup>(1)</sup> \$ m	Impairments <sup>(2)</sup>	Exceptional items <sup>(3)</sup>	Core results \$ m \$ m
Gross profit	4,356	368	18	4	4,746
Operating income	1,422	383	26	90	1,921
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,445)	368	18	4	(5,055)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(640)	15	7	(106)	(724)
Other income	88			(12)	76
Other expense	(422)		1	204	(217)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

<sup>(2)</sup> Impairments: Cost of goods sold and Research & Development include an impairment charge of intangible assets; Other expense include an impairment charge.

Exceptional items: Cost of goods sold and Other income include restructuring charges, respectively release, related to the Group-wide rationalization of manufacturing sites; Research & Development includes a reduction to a contingent consideration liability related to a business combination; Other income includes the release of a restructuring provision in Germany; Other expense includes a charge related to US litigations.

(4)

			A	cquisition		
				or		
			d	ivestment		
				related		
				items,		
	A	Amortization	res	structuring		
		of		and		
	IFRS	intangible	iı	ntegration E	xceptional	Core
$2010^{(1)}$	results	assets(2) Imp			items <sup>(5)</sup>	results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	3,997	278	4	12		4,291
Operating income	1,321	293	11	12	105	1,742
The following are adjustments to arrive at						
Core Gross Profit						
Cost of goods sold	(4,878)	278	4	12		(4,584)
The following are adjustments to arrive at						
Core Operating Income						
Research & Development	(658)	15	7		18	(618)
Other income	77		(1)			76
Other expense	(295)		1		87	(207)

(1) Restated to reflect new divisional segment allocation introduced during 2011.

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Cost of goods sold includes impairment charges for acquired rights to in-market products and other production-related impairment charges; Research & Development includes write-offs related to in-process Research & Development; Other income includes impairment reversals, primarily for property, plant & equipment; Other expense includes impairments, primarily for property, plant & equipment.

Acquisition-related restructuring and integration items: Cost of goods sold includes charges of \$4 million related to business acquisitions and \$8 million related to a required inventory step-up to estimated fair value related to the Falcon unit.

Exceptional items: Research & Development includes an expense for termination of a co-development contract; Other expense includes a \$49 million charge for a restructuring program in Germany and a \$38 million charge for a legal settlement in the US.

(3)

### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS VACCINES AND DIAGNOSTICS

				or livestment related		
	A	Amortization	re	items, structuring		
2012	IFRS results	of intangible assets <sup>(1)</sup> Im		and ntegration e	Other	Core results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	755	197		3	(56)	899
Operating income	(250)	215	12	3	(55)	(75)
The following are adjustments to arrive at Core Gross Profit						
Other revenues	331				(56)	275
Cost of goods sold	(1,478)	197		3		(1,278)
The following are adjustments to arrive at Core Operating Income						
Research & Development	(453)	18	5		1	(429)
Other expense	(115)		7			(108)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Research & Development includes impairments of intangible assets; Other expense includes a facility impairment charge and impairments of financial assets.

Acquisition or divestment related items, restructuring and integration charges: Cost of goods sold includes an acquisition related inventory step-up adjustment.

Other exceptional items: Other revenues include an income related to an intellectual property settlement and license agreement; Research & Development includes restructuring charges related to the Group-wide rationalization of manufacturing sites.

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	F	Amortizatio of		Acquisition or divestment related items, estructuring and	3	
2011	IFRS results	intangible assets <sup>(1)</sup>	Impairments <sup>(2</sup>	integrationF charges <sup>(3)</sup>	Exceptional items <sup>(4)</sup>	l Core results
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Gross profit	954	211	l	5	2	1,172
Operating income	(249)	231	145	5	3	135
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(1,410)	211		5	2	(1,192)
The following are adjustments to arrive at Core Operating Income						
Research & Development	(523)	20	8		1	(494)
Other expense	(185)		137			(48)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Research & Development includes an In Process Research & Development impairment charge; Other expense includes an impairment charge of a financial asset.

<sup>(3)</sup> Acquisition-related divestment gains, restructuring and integration charges: Cost of goods sold includes an acquisition related inventory step-up adjustment.

Exceptional items: Cost of goods sold and Research & Development adjustments represent restructuring charges related to the Group-wide rationalization of manufacturing sites.

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2010	IFRS results \$ m	Amortization of intangible assets <sup>(1)</sup> \$ m	Impairments <sup>(2)</sup> \$ m	Exceptional items <sup>(3)</sup>	Core results \$ m
Gross profit	1,860	242		2	2,104
Operating income	612	259	112	83	1,066
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(1,551)	242		2	(1,307)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(523)	17			(506)
Other expense	(273)		112	81	(80)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

Impairments: Other expense relates to a charge of \$98 million for an impairment of a financial asset and a charge of \$14 million for impairments for property, plant & equipment due to a restructuring program in the UK.

Exceptional items: Cost of goods sold includes charges related to inventory write-off due to a restructuring program; Other expense relates to a \$45 million expense for a legal settlement and to a \$36 million expense for a restructuring program in the UK.

### 2012, 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS CONSUMER HEALTH

2012	IFRS results \$ m	Amortization of intangible assets <sup>(1)</sup> \$ m	Impairments <sup>(2)</sup>	Other exceptional items <sup>(3)</sup> \$ m	Core results \$ m
Gross profit	2,050	57	7	25	2,139
Operating income	48	57	10	44	159
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(1,729)	57	7	25	(1,640)
The following are adjustments to arrive at Core Operating Income					
Other income	75			(8)	67
Other expense	(73)		3	27	(43)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets.

<sup>(2)</sup> Impairments: Cost of goods sold includes impairments of intangible assets; Other expense includes impairments of property, plant & equipment.

Other exceptional items: Cost of goods sold, Other income, and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold also includes an additional charge for product recalls related to a US production plant and an impairment of a long-term asset; Other income includes a restructuring provision release; Other expense includes a legal settlement related to a US production plant.

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2011	IFRS results \$ m	Amortization of intangible assets <sup>(1)</sup> \$ m	Impairments <sup>(2)</sup>	Exceptional items <sup>(3)</sup>	Core results \$ m
Gross profit	2,935	58	11	105	3,109
Operating income	727	59	16	71	873
The following are adjustments to arrive at Core Gross Profit					
Net sales to third parties	4,631			73	4,704
Cost of goods sold	(1,735)	58	11	32	(1,634)
The following are adjustments to arrive at Core Operating Income					
Marketing & Sales	(1,674)			2	(1,672)
Research & Development	(296)	1	3		(292)
Other income	91			(44)	47
Other expense	(38)		2	8	(28)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

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Impairments: Cost of goods sold includes an impairment charge related to Consumer Health in the US; Research & Development and Other expense include impairment charges.

Exceptional items: Net sales to third parties includes an over-the-counter products recall provision; Cost of goods sold and Marketing & Sales include charges related to Consumer Health in the US; Other income includes a product divestment gain; Other expense includes charges related to the Group-wide rationalization of manufacturing sites and other restructuring charges.

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2010 <sup>(1)</sup>	IFRS results \$ m	Amortization of intangible assets <sup>(2)</sup> \$ m	Impairments <sup>(3)</sup> \$ m	Core results \$ m
Gross profit	2,871	60	6	2,937
Operating income	778	61	6	845
The following are adjustments to arrive at Core Gross Profit				
Cost of goods sold	(1,560)	60	6	(1,494)
The following are adjustments to arrive at Core Operating Income				
Marketing & Sales	(1,569)	1		(1,568)

<sup>(1)</sup> Restated to reflect new divisional segment allocation introduced during 2011.

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Marketing & Sales includes the recurring amortization of intangible assets.

<sup>(3)</sup>Impairments: Cost of goods sold includes impairment charges for acquired rights to in-market products and other production-related impairment charges.

2012 and 2011 Reconciliation of segment operating income to Core operating income

	Pharmace	uticols	Alco	<b>.</b>	Sand	loz	Vacci and Diagno	i	Consu Heal		Corpo	mata	Tota	
							U				•			
	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m	2012 \$ m	2011 \$ m
	ъщ	Ş III	ъШ	φШ	ъШ	ъщ	ъщ	ъщ	ъш	\$ III	ЭШ	<b>Э</b> Ш	ъш	ъщ
Operating income	9,598	8,296	1,465	1,472	1,091	1,422	(250)	(249)	48	727	(441)	(670)	11,511	10,998
Amortization of intangible assets	322	423	1,915	1,928	364	383	215	231	57	59	3	4	2,876	3,028
Impairments														
Intangible assets	211	552	17	20	43	25	5	8	7	14			283	619
Property, plant & equipment related to the Group-wide rationalization of manufacturing sites		12		5										17
Other property, plant &		12		3										17
equipment	25	391			3	1	6	2	3	2	2		39	396
Financial assets	2	30		4			1	135			31	23	34	192
Total impairment charges	238	985	17	29	46	26	12	145	10	16	33	23	356	1,224
Acquisition-related items														
Gains		(81)		(21)										(102)
Expenses			264	233	62		3	5			1	12	330	250
Total acquisition-related items, net		(81)	264	212	62		3	5			1	12	330	148
Other exceptional items Exceptional divestment														
gains Restructuring items	(93)	(334)								(44)	(51)		(144)	(378)
Income	(70)		(1)		(10)	(12)			(8)				(89)	(12)
Expense	240	420	24	52	4	4	1	3	3	8			272	487
Legal-related items Income		(100)		(229)										(329)
Expense	19	80		45		204			25				44	329
Additional exceptional		00												027
income	(137)			(17)	(59)	(106)	(56)					(85)	(252)	(208)
Additional exceptional expense	96	351	14		5				24	107	117	164	256	622
Total other exceptional items	55	417	37	(149)	(60)	90	(55)	3	44	71	66	79	87	511
				,	( /	-	()							
Total adjustments	615	1,744	2,233	2,020	412	499	175	384	111	146	103	118	3,649	4,911
Core operating income	10,213	10,040	3,698	3,492	1,503	1,921	(75)	135	159	873	(338)	(552)	15,160	15,909
Core return on net sales	31.8%	30.9%	36.2%	35.1%	17.3%	<b>20.3</b> % 182	-4.0%	6.8%	4.3%	18.9%			26.7%	27.2%

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2011 and 2010 Reconciliation of segment operating income to Core operating income

							Vacci		Consui	mer				
	Pharmace	uticals	Alcon,	Inc.	Sand	oz	Diagno		Heal		Corpo	orate	Tota	al
	2011	2010	2011	2010(2)	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010
	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m	\$ m
Operating income	8,296	8,471	1,472	<b>796</b>	1,422	1,321	(249)	612	727	778	(670)	(452)	10,998	11,526
Amortization of intangible	400		4.000		202		-24		=0				2.020	4 40=
assets	423	457	1,928	65	383	293	231	259	59	61	4		3,028	1,135
Impairments														
Intangible assets	552	796	20		25	11	8		14	6			619	813
Property, plant & equipment related to the Group-wide													7.7	
rationalization of														
manufacturing sites	12		5					14					17	14
Other property, plant &														
equipment	391	(4)			1		2	0.0	2			40	396	(4)
Financial assets	30	41	4				135	98			23	19	192	158
Total impairment charges	985	833	29		26	11	145	112	16	6	23	19	1,224	981
Acquisition-related items														
Gains	(81)		(21)										(102)	
Expenses			233	489		12	5				12	99	250	600
Total acquisition-related items, net	(81)		212	489		12	5				12	99	148	600
Other exceptional items														
Exceptional divestment														
gains	(334)	(425)							(44)				(378)	(425)
Restructuring items	(1)	(T)			(10)								(10)	(7)
Income Expense	(1) 421	(7) 118	52		(12)	49	3	38	8				(13) 488	(7) 205
Legal-related items	421	110	32		4	47	3	30	o				400	203
Income	(100)	(42)	(229)										(329)	(42)
Expense	80	181	45		204	56		45					329	282
Swiss pension curtailment														
gain												(265)		(265)
Additional exceptional			(17)		(100)						(0.5)		(200)	
income Additional exceptional			(17)		(106)						(85)		(208)	
expense	351								107		164	16	622	16
препос	001								107		10.	10	022	10
Total other exceptional items	417	(175)	(149)		90	105	3	83	71		79	(249)	511	(236)
Total adjustments	1,744	1,115	2,020	554	499	421	384	454	146	67	118	(131)	4,911	2,480
Core operating income	10,040	9,586	3,492	1,350	1,921	1,742	135	1,066	873	845	(552)		15,909	14,006
Core return on net sales	30.9%	31.6%	35.1%	30.4%	20.3%	20.3%	6.8%	36.5%	18.9%	19.4%			27.2%	27.7%

<sup>(1)</sup>Restated to reflect new divisional segment allocation introduced during 2011. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

Consolidated results of Alcon, Inc., only included for the period from acquiring control on August 25, 2010 to December 31, 2010. Ophthalmic activities transferred from Pharmaceuticals and CIBA Vision transferred from Consumer Health included for the full year.

Related to the Group-wide rationalization of manufacturing sites (Swiss portion amounts to approximately \$100 million).

#### ALCON SEGMENT RECONCILIATION FROM 2010 RESTATED TO PRO FORMA DATA

(3)

On August 25, 2010 Novartis acquired a majority interest in Alcon, Inc. and its results have been included in the consolidated IFRS results of the Novartis Group and the Alcon segment since then (for additional information, see "Item 18, Financial Statements" note 2").

Novartis believes that the presentation of pro forma information will assist investors in their understanding of the combined companies' operating performance by setting a base for comparison with the 2011 consolidated results of Alcon. Without these pro forma results, the Alcon 2010 restated results through August 25, 2010 would consist only of the results from CIBA Vision and those Pharmaceuticals ophthalmics products which were transferred to Alcon. As a result, it is considered a comparison between the 2011 Alcon results and the 2010 restated results would not be meaningful.

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Therefore Novartis prepared pro forma information assuming the Alcon acquisition was completed on January 1, 2010. The pro forma information does not purport to present what the actual results of operations would have been had the transaction actually occurred on the date indicated.

The pro forma information includes the full 2010 consolidated income statement data for Alcon, Inc. from January 1, 2010 and adjusts for the impact of divestments required by regulators to approve the Alcon acquisition as well as for exceptional costs related to the acquisition of majority ownership of Alcon.

The following tables reconcile IFRS to pro forma core results for Alcon:

		Consolidated results of Alcon, Inc., from Jan. 1, 2010	
	2010	to Aug. 25,	2010
(in \$ m)	Restated	$2010^{(1)}$	Pro forma
Net sales to third parties	4,446	4,585	9,031
Sales to other segments	14		14
Net sales of segments	4,460	4,585	9,045
Other revenues	34	5	39
Cost of goods sold	(1,760)	(2,442)	(4,202)
-			
Gross profit	2,734	2,148	4,882
Marketing & Sales	(1,299)	(1,060)	(2,359)
Research & Development	(352)	(478)	(830)
General & Administration	(255)	(255)	(510)
Other income	7		7
Other expense	(39)	30	(9)
Operating income	796	385	1,181
as % of net sales	17.9%	8.4%	13.1%
Core adjustments			
Cost of goods sold	519	1,379	1,898
Research & Development	1	3	4
General & Administration	4	8	12
Other expense	30	(30)	
Core Operating income	1,350	1,745	3,095
as % of net sales	30.4%	38.1%	34.3%

This assumes that the acquisition of Alcon, Inc. had occured on January 1, 2010. It therefore also reflects \$1.4 billion of additional amortization of intangible assets arising from the purchase price allocation and excludes \$145 million of change of control and acquisition related costs.

(1)

# RECONCILIATION OF ALCON PRO FORMA FROM AMENDMENT NO.3 TO FORM F-4, FILED WITH THE US SEC ON FEBRUARY 24, 2011, TO ANNUAL REPORT 2011

(in \$ m)		2010
Alcon operating income as reported in IFRS by Novartis (August 25, 2010 December 31, 2010)		323
Alcon income statement under IFRS as adopted by Novartis (January 1, 2010 December 31, 2010)	2,501	
Purchase price allocation and other pro forma adjustments (including elimination of double-counting of Alcon for		
August 25, 2010 December 31, 2010)	(2,016)	
Pro forma as reported in F4 on February 24, 2011		485
·		
Acquisition costs recorded in Corporate and therefore not to be taken into account in Alcon Division operating		
income		(99)
Falcon operating income transferred to Sandoz	(43)	
CIBA Vision operating income transferred from Consumer Health	383	
Ophthalmics products related operating income transferred to Alcon	132	
Segments transfers		472
g <del>g</del>		
Alcon pro forma operating income		1,181

### 2011 AND 2010 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS ALCON PRO FORMA

2011	IFRS results \$ m	Amortization of intangible assets <sup>(1)</sup> In \$ m	mpairments <sup>(</sup> \$ m	0	g Exceptional items <sup>(4)</sup> \$ m	Core results \$ m
Gross profit	5,453	1,912	·	·	20	7,385
Operating income	1,461	1,928	29	221	(149)	3,490
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(4,561)	1,912			20	(2,629)
The following are adjustments to arrive at Core Operating Income						
Research & Development	(892)	3	20			(869)
General & Administration	(509)	13				(496)
Other income	241				(229)	12
Other expense	(296)		9	221	60	(6)

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets.

(2)

Impairments: Research & Development includes an In Process Research & Development impairment charge; Other expense includes impairment charges primarily related to the Group-wide rationalization of manufacturing sites.

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(3) Acquisition-related divestment gains, restructuring and integration charges: Other expense relates to Alcon integration costs.

Exceptional items: Cost of goods sold and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold includes a reduction to a contingent consideration provision related to a business combination; Other income and expense includes a net \$183 million gain from the Jump litigation settlement.

2010 <sup>(1)</sup>	IFRS results \$ m	Amortization of intangible assets <sup>(2)</sup> \$ m	Core results \$ m
Gross profit	4,882	1,898	6,780
Operating income	1,181	1,914	3,095
The following are adjustments to arrive at Core Gross Profit			
Cost of goods sold	(4,202)	1,898	(2,304)
The following are adjustments to arrive at Core Operating Income			
Research & Development	(830)	4	(826)
General & Administration	(510)	12	(498)

On a pro forma basis. For additional information, see "Non-IFRS measures as defined by Novartis Alcon segment reconciliation from 2010 restated to pro forma data".

### NOVARTIS ECONOMIC VALUE ADDED

Novartis utilizes its own definition for measuring Novartis Economic Value Added (NVA), which is utilized for determining payouts under the Long-Term Performance Plan. NVA is a non-IFRS metric and may not be comparable to the calculation of similar measures of other companies. This measure is presented solely to permit investors to more fully understand how the Group's management is compensated. The following table shows NVA for 2012 and 2011 utilizing the Novartis definition.

	Year ended December 31, 2012 \$ m	Year ended December 31, 2011 \$ m	Change in \$
Operating income	11,511	10,998	5
Income from associated companies	552	528	5
Operating interest	(348)	(284)	23
Operating tax	(2,334)	(2,296)	2
Capital charge	(7,060)	(7,397)	(5)
Novartis Economic Value Added	2,321	1,549	50

Operating interest is the internal charge on average working capital based on the short-term borrowing rates of the entity owning them.

Operating tax is the internal tax charge for each entity applying the applicable tax rate to the profit before tax of each entity unadjusted for tax-disallowed items or tax loss carryforwards.

Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; General & Administration includes the recurring amortization of intangible assets.

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The capital charge is the notional interest charge on the Group's average non-current assets based on an internally calculated weighted average cost of capital for the Group.

### 5.B Liquidity and Capital Resources

#### **Cash Flow**

The following table sets forth certain information about the Group's cash flow and net debt/liquidity.

	2012	2011	2010
	\$ m	\$ m	\$ m
Cash flows from operating activities	14,194	14,309	14,067
Cash flows used in investing activities	(5,675)	(792)	(15,756)
Cash flows used in financing activities	(6,675)	(15,024)	4,116
Currency translation effect on cash and cash equivalents	(1)	(103)	(2)
Net change in cash and cash equivalents	1,843	(1,610)	2,425
Change in marketable securities	1,201	(1,449)	(11,740)
Change in current and non-current financial debt	503	2,758	(8,999)
Change in net debt	3,547	(301)	(18,314)
Net debt at January 1	(15,154)	(14,853)	3,461
Net debt at December 31	(11,607)	(15,154)	(14,853)

### Financial year 2012

In 2012, cash flow from operating activities amounted to \$14.2 billion, only marginally lower than the prior year amount of \$14.3 billion as the impact of lower tax payments was offset by the payments from provisions created in earlier periods.

The cash flow used in investing activities amounted to \$5.7 billion, \$4.9 billion higher than 2011, which primarily reflected the amount spent for the acquisition of Fougera Pharmaceuticals, Inc. (\$1.5 billion) and net investments in property, plant and equipment and other non-current assets, which amounted to \$2.8 billion, while the net investment in marketable securities amounted to \$1.1 billion. In 2011, the impact of the net investments in property, plant and equipment and in other non-current assets (\$1.8 billion), as well as the cash used for acquisitions (\$0.6 billion), were partially offset by the net proceeds from the sale of marketable securities (\$1.6 billion).

In 2012, the cash used in financing activities amounted to \$6.7 billion mainly on account of the dividend payment (\$6.0 billion) and \$0.5 billion net repayment of financial debt. This is a decrease of \$8.3 billion compared to the prior year period. In 2011, the cash flow used in financing activities amounted to \$15.0 billion mainly on account of the dividend payment (\$5.4 billion), treasury share transactions (\$3.5 billion), the acquisition of the non-controlling interest in Alcon (\$3.2 billion) and \$2.8 billion for the net repayment of financial debt.

### Financial year 2011

In 2011, the cash flow from operating activities was \$14.3 billion, a 2% increase from \$14.1 billion in 2010 which included \$1.8 billion of cash collections for A (H1N1) pandemic flu vaccines.

The strong increase in operating income after adjustments for non-cash items was partially mitigated by working capital requirements to fund business expansion.

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Cash outflows for investing activities were \$0.8 billion compared to \$15.8 billion in the prior year period. Outflows for investments in property, plant and equipment (\$2.2 billion) and intangible and financial assets (\$0.4 billion) as well as acquisition of businesses (\$0.6 billion), mainly Genoptix Inc., were partly compensated by net inflows from the sale of marketable securities (\$1.6 billion) and proceeds from the sales of various assets (\$0.8 billion, mainly Elidel® marketing rights).

In the prior year period, outflows for investments in property, plant and equipment (\$1.7 billion) and in intangible and financial assets (\$0.7 billion) as well as acquisition of businesses (\$26.7 billion), mainly Alcon, were partially funded by the sale of marketable securities (net, \$12.6 billion) and proceeds from the sales of various assets (\$0.7 billion).

Net cash used for financing activities was \$15.0 billion in 2011. It was comprised of outflows of \$5.4 billion for the dividend payment, of a net \$3.5 billion for treasury share repurchases, \$3.2 billion for the acquisition of the Alcon non-controlling interests and net \$2.8 billion for the repayment of financial debt and \$0.1 billion other financing items. In 2010, the financing activities resulted in a net cash inflow of \$4.1 billion on account of additional debt raised for the increased Alcon investment.

### Financial year 2010

Cash flow from operating activities was \$14.1 billion in 2010, a 15% increase from \$12.2 billion in 2009. The additional cash flow of \$1.9 billion generated by the strong business expansion and lower working capital requirements was partially offset by higher taxes and payments in connection with the resolution of certain legal matters.

The net cash outflow used for investing activities in 2010 amounted to \$15.8 billion, \$1.5 billion above the prior-year amount. The cash used for acquisitions was \$26.7 billion. This amount is comprised of \$26.1 billion (net of \$2.2 billion cash acquired) for the purchase of the additional 52% investment in Alcon and of \$0.5 billion for the acquisition of Corthera and Oriel as well as for deferred payments related to the EBEWE acquisition. The net cash used for investments in property, plant & equipment, intangible and other assets amounted to \$1.7 billion. These outflows were partially offset by the net proceeds of marketable securities of \$12.6 billon.

Net cash provided by financing activities increased by \$1.3 billion to \$4.1 billion in 2010 compared to \$2.8 billion in 2009. The \$8.3 billion proceeds from the bonds and commercial paper programs as well as other net inflows totaling \$0.3 billion were partially offset by the payment of the 2009 dividend of \$4.5 billion in 2010.

#### **Condensed Consolidated Balance Sheets**

	Dec 31, 2012	Dec 31, 2011	Change
	\$ m	\$ m	\$ m
Assets			
Property, plant and equipment	16,939	15,627	1,312
Goodwill	31,090	29,943	1,147
Intangible assets other than goodwill	30,331	31,969	(1,638)
Financial and other non-current assets	17,852	15,873	1,979
Total non-current assets	96,212	93,412	2,800
Inventories	6,744	5,930	814
Trade receivables	10,051	10,323	(272)
Other current assets	3,090	2,756	334
Cash, short-term deposits and marketable securities	8,119	5,075	3,044
Total current assets	28,004	24,084	3,920
Total assets	124,216	117,496	6,720
Total assets	124,210	117,490	0,720
Equity and liabilities			
Total equity	69,219	65,940	3,279
- •	·	•	·
Financial debt	13,781	13,855	(74)
Other non-current liabilities	17,165	14,553	2,612
Total non-current liabilities	30,946	28,408	2,538
	,	ĺ	
Trade payables	5,593	4,989	604
Financial debt and derivatives	5,945	6,374	(429)
Other current liabilities	12,513	11,785	728
Total current liabilities	24,051	23,148	903
Total liabilities	54,997	51,556	3,441
Total equity and liabilities	124,216	117,496	6,720
Total equity and liabilities	124,216	117,496	6,720

Total non-current assets have increased during the year by \$2.8 billion to \$96.2 billion at December 31, 2012 as a result of investments in manufacturing and R&D capabilities as well as the Fougera acquisition.

Total current assets increased by \$3.9 billion to \$28.0 billion at December 31, 2012 mainly due to an increase in cash, short-term deposits and marketable securities of \$3.0 billion. Inventory increased by \$0.8 billion to \$6.7 billion while trade receivables of \$10.1 billion were slightly below last year's level.

Trade receivable balances include sales to drug wholesalers, retailers, private health systems, government agencies, managed care providers, pharmacy benefit managers and government-supported healthcare systems. We continue to monitor sovereign debt issues and economic conditions in Europe, in particular in Greece, Italy, Portugal, and Spain (GIPS countries), and evaluate accounts receivable in these countries for potential collection risks. A number of actions were taken to limit our credit risk exposure in these countries, including factoring without recourse and negotiating settlements with the governments or local authorities where we consider this makes economic sense. Deteriorating credit and economic conditions in these countries, among other factors may continue to result in an increase in the average length of time that it takes to collect these accounts receivables.

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Based on our current incurred loss provisioning approach we consider that our doubtful debt provisions are adequate. However, we intend to continue to monitor the level of trade receivables in the GIPS countries. Should there be a substantial deterioration in our economic exposure, we may increase our level of provisions by moving to an expected loss provisioning approach or change terms of trade on which we operate.

The following table provides an overview of our aging analysis of our accounts receivable as of December 31, 2012 and 2011:

	2012	2011
	\$ m	\$ m
Not overdue	8,584	8,967
Past due for not more than one month	552	498
Past due for more than one month but less than three months	321	295
Past due for more than three months but less than six months	301	249
Past due for more than six months but less than one year	205	228
Past due for more than one year	305	305
Provisions for doubtful trade receivables	(217)	(219)
Total trade receivables, net	10,051	10,323

With regard to the GIPS countries, the country with the largest outstanding trade receivables exposure is Italy. Substantially all of the outstanding trade receivables from this country are due directly from local governments or from government-funded entities. The movement in the outstanding trade receivables from this country during the year and the related outstanding accounts receivable and provision at December 31, 2012 and 2011 is as follows:

	2012	2011
	\$ m	\$ m
Gross trade receivables at December 31	712	761
Past due for more than one year at December 31	68	91
Provision at December 31	37	28

Other non-current liabilities amounted to \$17.2 billion compared to \$14.6 billion in the prior year. A major portion of this increase of \$2.6 billion arose from the increase in the accrued liability for employee benefits related to our funded and unfunded defined benefit pension plans around the world, but principally in Switzerland and the United States, as well as unfunded and funded US post-retirement medical benefit schemes. The net unfunded deficit of \$6.3 billion related to the defined benefit schemes comprises actuarially determined liabilities of \$26.8 billion partially offset by funded plan assets of \$20.5 billion.

This deficit adjusted for non-vested past service costs as well as for the overfunding of certain plans is recognized in our provisions and fluctuates considerably from time to time. This is due to the fact that the assets consist of both marketable securities and other investments which are valued at their current market value. The actuarially calculated post-employment defined benefit obligations of \$26.8 billion have an average duration of 14.1 years and are extremely sensitive to movements in discount rates which are currently at a historic low. The movements in these obligations are the principal reason for the increase in the provision by \$2.3 billion over the year.

Trade payables of \$5.6 billion and other current liabilities of \$12.5 billion increased by \$0.6 billion and \$0.7 billion respectively.

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Included in other current liabilities are \$2.1 billion relating to outstanding taxes. While there is some uncertainty about the final taxes to be assessed in our major countries, we consider this uncertainty to be limited since our tax assessments are generally relatively current. In our key countries, Switzerland and the United States, assessments have been agreed by the tax authorities up to 2009 and 2006, respectively.

The Group's total equity rose to \$69.2 billion as of December 31, 2012, compared to \$65.9 billion at the end of 2011.

This increase is driven by comprehensive income of \$8.6 billion, consisting of net income of \$9.6 billion, net actuarial losses from defined benefit plans of \$1.8 billion and positive currency translation effects of \$0.8 billion and an increase of \$0.9 billion related to share-based compensation. These were partially offset by the dividend payment of \$6.0 billion, with net sales of treasury shares and changes in non-controlling interests contributing an additional reduction of \$0.2 billion.

#### Liquidity

As a result of the strong cash flow generation, the Group liquidity increased over the year to \$8.1 billion at December 31, 2012 from \$5.1 billion at the prior year end even after repayment of the CHF 700 million bond that matured in 2012. The Group liquidity consists of \$5.5 billion cash and cash equivalents and of \$2.6 billion marketable securities and derivative financial instruments.

At December 31, 2011, the Group liquidity amounted to \$5.1 billion compared to \$8.1 billion at the end of 2010 and consists of \$3.7 billion cash and cash equivalents and of \$1.4 billion marketable securities and derivative financial instruments.

At December 31, 2010, the Group liquidity amounted to \$8.1 billion and consists of \$5.3 billion cash and cash equivalents and of \$2.8 billion marketable securities and derivative financial instruments.

#### **Net Debt**

As of December 31, 2012, our total gross short and long-term debt was \$19.7 billion, as compared with \$20.2 billion as of December 31, 2011 and \$23.0 billion as of December 31, 2010. Total gross short and long-term debt in 2012 decreased compared to 2011 by \$0.5 billion. Total gross short and long-term debt in 2011 decreased compared to 2010 by \$2.8 billion despite the funding of acquisitions and share repurchases.

We have \$14.8 billion of bonds and Medium Term Notes and other long-term financial loans of \$1.0 billion outstanding at December 31, 2012. We had \$13.5 billion and \$13.5 billion of bonds and Medium Term Notes outstanding at December 31, 2011 and at December 31, 2010, respectively. We had \$1.1 billion and \$1.0 billion of other long-term financial loans outstanding at December 31, 2011 and at December 31, 2010, respectively. For details on the maturity profile of debt, currency and interest rate structure, see "Item 18. Financial Statements" note 19".

As of December 31, 2012, we had current debt (excluding the current portion of non-current debt) of \$3.9 billion as compared with \$5.6 billion as of December 31, 2011, and \$8.5 billion as of December 31, 2010. This current debt consists mainly of \$2.8 billion (2011: \$3.4 billion, 2010: \$3.5 billion) in other bank and financial debt, including interest bearing employee accounts, \$963 million (2011: \$2.2 billion, 2010: \$5.0 billion) of commercial paper and \$162 million (2011: \$30 million, 2010: \$44 billion) of other current debt. For further details see "Item 18. Financial Statements note 21".

Our net debt decreased to \$11.6 billion at the end of 2012 from a net debt of \$15.2 billion at the end of 2011. At the end of 2010 the net debt amounted to \$14.9 billion.

Novartis strives to maintain a strong credit rating. In managing its capital, Novartis focuses on a strong balance sheet. Credit agencies in 2012 maintained their ratings for Novartis. Moody's rated the Group as Aa2 for long-term maturities and P-1 for short-term maturities and Standard & Poor's had a

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rating of AA- for long-term and A-1+ for short-term maturities. Fitch had a long-term rating of AA and a short-term rating of F1+.

The 2012 year-end debt/equity ratio decreased to 0.28:1 from 0.31:1 in 2011 principally due to less current financial debt being outstanding under the commercial paper programs.

We are in compliance with all covenants or other requirements set forth in our financing agreements. We do not have any rating downgrade triggers that would accelerate maturity of our debt. For details of the maturity profile of debt, currency and interest rate structure, see "Item 18. Financial Statements" note 19".

Net debt/liquidity constitutes a non-IFRS financial measure, which means that it should not be interpreted as a measure determined under International Financial Reporting Standards (IFRS). Net debt/liquidity is presented as additional information as it is a useful indicator of the Group's ability to meet financial commitments and to invest in new strategic opportunities, including strengthening its balance sheet.

We use marketable securities and derivative financial instruments to manage the volatility of our exposures to market risk in interest rates and liquid investments. Our objective is to reduce, where appropriate, fluctuations in earnings and cash flows. We manage these risks by selling existing assets or entering into transactions and future transactions (in the case of anticipatory hedges) which we expect we will have in the future, based on past experience. We therefore expect that any loss in value for those securities or derivative financial instruments generally would be offset by increases in the value of those hedged transactions.

We use the US dollar as our reporting currency and we are therefore exposed to foreign exchange movements, primarily in European, Japanese and other Asian and Latin American currencies. Consequently, we enter into various contracts which change in value as foreign exchange rates change, to preserve the value of assets, commitments and anticipated transactions. We also use forward contracts and foreign currency option contracts to hedge certain anticipated net revenues in foreign currencies.

The following table provides a breakdown of liquidity and financial debt by currency:

	Liquidity in % 2012	Liquidity in % 2011	Liquidity in % 2010	Financial debt in % 2012	Financial debt in % 2011	Financial debt in % 2010
\$	72	60	82	63	56	64
EUR	5	2	3	11	13	13
CHF	15	33	11	13	15	13
JPY				10	14	8
Other	8	5	4	3	2	2
	100	100	100	100	100	100

#### Free Cash Flow

Novartis defines free cash flow as cash flow from operating activities less purchase or sale of property, plant & equipment, intangible, other non-current and financial assets. Cash flows in connection with the acquisition or divestment of subsidiaries, associated companies and non-controlling interests are excluded

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from free cash flow. For further information see "Non-IFRS measures as defined by Novartis Free Cash Flow". The following is a summary of the Group's free cash flow:

	2012 \$ m	2011 \$ m	2010 \$ m
Operating income	11,511	10,998	11,526
Reversal of non-cash items	,	,	,
Depreciation, amortization and impairments	4,954	5,980	3,577
Change in provisions and other non-current liabilities	539	1,295	802
Other	452	272	226
Operating income adjusted for non-cash items	17,456	18,545	16,131
Interest and other financial receipts	689	470	741
Interest and other financial payments	(616)	(687)	(670)
Taxes paid	(2,022)	(2,435)	(2,616)
Payments out of provisions and other net cash movements in non-current liabilities	(1,173)	(1,471)	(1,281)
Change in inventory and trade accounts receivable less accounts payable	183	(492)	1,481
Change in other net current assets and other operating cash flow items	(323)	379	281
Cash flows from operating activities	14,194	14,309	14,067
Purchase of property, plant and equipment	(2,698)	(2,167)	(1,678)
Purchase of intangible assets	(370)	(220)	(554)
Purchase of financial assets	(180)	(139)	(124)
Purchase of other non-current assets	(57)	(48)	(15)
Proceeds from sales of property, plant and equipment	92	61	36
Proceeds from sales of intangible assets	163	643	545
Proceeds from sales of financial assets	221	59	66
Proceeds from sales of other non-current assets	18	5	3
Group free cash flow	11,383	12,503	12,346

### Financial year 2012

In 2012, the free cash flow of \$11.4 billion was \$1.1 billion lower than the prior year mainly on account of higher investments in property, plant and equipment of \$2.7 billion compared to \$2.2 billion (4.8% of net sales compared to 3.7% in 2011) and lower divestment proceeds which amounted to \$0.5 billion in 2012 compared to \$0.8 billion in 2011.

This free cash flow was primarily used for dividend payments to shareholders of \$6.0 billion (compared to \$5.4 billion in 2011), for the recent acquisitions which on a net cash basis amounted to \$1.7 billion (mainly Fougera Pharmaceuticals, Inc.), and for the reduction of net debt of \$3.5 billion. This allocation reflects management's intention to optimize shareholder returns whilst at the same time reinvesting surplus fund in the business to assure future growth.

### Financial year 2011

Free cash flow for 2011 was \$12.5 billion, which represents an increase of 1% or \$0.2 billion compared to 2010. Main contributors were Pharmaceuticals with \$10.8 billion followed by Alcon with \$3.5 billion while other divisions contributed in total \$2.1 billion. Corporate had a free cash outflow of \$3.9 billion mainly on account of interest and tax payments. Free cash flow of \$12.5 billion was deployed for dividend payments of \$5.4 billion and share repurchases of \$5.9 billion (including \$2.4 billion repurchased indirectly via Alcon, Inc. to reduce the dilutive impact of the subsequent merger of

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Alcon, Inc. into Novartis AG). In total, dividends and share repurchases utilized 90% of the Group's 2011 free cash flow.

#### Financial year 2010

The free cash flow for 2010 was \$12.3 billion, which represents an increase of 30.7% over 2009. The strong business expansion, lower working capital requirements, higher proceeds from the disposal of intangible assets as well as lower capital spending contributed to the growth of the free cash flow. Net investments in property, plant & equipment in 2010 were \$1.6 billion, or 3.2% of net sales, down from 4.2% of net sales in 2009. Free cash flow in 2010 was mainly attributable to the Pharmaceuticals Division which contributed \$10.7 billion to the Group total.

Free cash flow is presented as additional information because Novartis considers it is a useful indicator of the Group's ability to operate without relying on additional borrowing or the use of existing cash. Free cash flow is a measure of the net cash generated that is available for debt repayment and investment in strategic opportunities. The Group uses free cash flow as a performance measure when making internal comparisons of the results of divisions. Free cash flow constitutes a non-IFRS financial measure, which means that it should not be interpreted as a measure determined under IFRS. Free cash flow is not intended to be a substitute measure for cash flow from operating activities (as determined under IFRS).

#### **Capital Resources**

### Funding of the Alcon transaction 2010

On August 25, 2010, Novartis completed the acquisition of a further 52% interest in Alcon, Inc. following on from the January 4, 2010 announcement that Novartis had exercised its call option to acquire Nestlé's remaining 52% Alcon interest for approximately \$28.3 billion or \$180 per share. This increased the interest in Alcon to a 77% controlling interest as Novartis had already acquired an initial 25% Alcon interest from Nestlé for \$10.4 billion or \$143 per share in July 2008.

On December 14, 2010, Novartis entered into a definitive agreement to merge Alcon into Novartis for Novartis shares and a Contingent Value Amount (CVA). Under the terms of the agreement, the merger consideration will include up to 2.8 Novartis shares and a CVA to be settled in cash that will in aggregate equal \$168 per share. If the value of 2.8 Novartis shares is more than \$168 the number of Novartis shares will be reduced accordingly. The total merger consideration for the non-controlling interest will be \$12.9 billion, comprising of up to 215 million Novartis shares and a potential CVA to be settled in cash.

The overall purchase price of \$38.7 billion includes certain adjustments for Alcon dividends and interest due. Sources of financing for the 77% ownership, including the initial 25% stake purchased in mid-2008, were \$17.0 billion of available cash, and \$13.5 billion from bonds raised in March 2010 as well as in 2008 and 2009. In addition, during 2010, we raised funds of \$8.2 billion through our commercial paper program, which was used for general corporate purposes of the Novartis Group, as well as for intercompany financing purposes in connection with the acquisition of the 52% interest in Alcon.

#### Funding of the Alcon transaction 2011

During 2011, prior to the merger of Alcon, Inc. into Novartis AG on April 8, 4.8% of the non-controlling interests in Alcon, Inc. were acquired for \$2.4 billion.

Completion of the acquisition of the outstanding 18.6% interest in Alcon on April 8, 2011 and subsequent merger, resulted in the issuance of Novartis shares with a fair value of \$9.2 billion and a contingent value payment of \$0.5 billion.

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The final purchase price allocation was completed in 2011 and resulted in a fair value of net identifiable assets of \$27.0 billion and goodwill of \$18.0 billion. Also, the excess of the value exchanged for these 2011 transactions over the recorded value of the non-controlling interest together with merger related transaction costs resulted in a reduction in equity of \$5.7 billion.

For additional information, see "Item 18, Financial Statements" note 2 and 24".

#### Share Repurchase Plans

During 2012, Novartis repurchased 4.6 million of its shares for \$240 million on the first trading line on the SIX. These shares will be kept as treasury shares principally for future employee participation program purposes. Following the approval of our shareholders at the Annual General Meeting on February 23, 2012, all shares repurchased on the second trading line of the SIX during 2011 were cancelled (total of 39.4 million shares, which corresponded to 1.4% of the registered Novartis share capital), and the share capital was reduced accordingly.

In 2011, Novartis has carried out the share repurchases committed to at the time of the Alcon merger announcement. These share repurchases amounted to \$5.3 billion including the purchases of \$2.4 billion of Alcon shares, a contingent value payment of \$0.5 billion and repurchases of \$2.4 billion of Novartis shares (39.4 million shares). All of these Novartis shares were repurchased on the second trading line during the first six months of 2011. In addition, in the second half of 2011, Novartis repurchased \$1.1 billion (20.4 million shares) of own shares on the first trading line. These shares will be kept as treasury shares to mostly cover future employee participation programs.

No shares were cancelled in 2011 as none had been repurchased in the 12 months to December 2010.

#### Treasury shares

At December 31, 2012, our holding of treasury shares amounted to 285.6 million shares or 11% of the total number of issued shares. Approximately 175 million treasury shares are held in entities that limit their availability for use.

At December 31, 2011, our holding of treasury shares amounted to 338.9 million shares or 12% of the total number of issued shares. Approximately 181 million treasury shares are held in entities that limit their availability for use.

At December 31, 2010, our holding of treasury shares amounted to 348.2 million shares or 13% of the total number of issued shares. Approximately 181 million treasury shares are held in entities that limit their availability for use.

#### **Bonds**

In September 2012, a \$2.0 billion bond offering was completed in the United States. Two tranches were issued, one 10-year bond of \$1.5 billion with a coupon of 2.4% and the other at \$0.5 billion 30-year bond with a coupon of 3.7%. Further, a 3.5% Swiss franc bond of CHF 700 million was repaid in 2012.

In 2011 no bonds were issued or repaid.

On March 9, 2010, Novartis issued a three-tranche bond totaling \$5.0 billion registered with the US Securities and Exchange Commission as part of a shelf registration statement filed by Novartis in 2008. A 1.9% three-year tranche totaling \$2.0 billion, a 2.9% five-year tranche totaling \$2.0 billion and a 4.4% 10-year tranche totaling \$1.0 billion were issued by the Group's US entity, Novartis Capital Corp. All tranches are unconditionally guaranteed by Novartis AG.

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#### Direct Share Purchase Plans

Since 2004, Novartis has offered a Direct Share Purchase Program to investors residing in Switzerland, Liechtenstein, France and the United Kingdom, which was the first of its kind in Europe. This plan offers an easy and inexpensive way for investors to directly purchase Novartis registered shares and for them to be held at no cost in a deposit account with SIX SAG AG. At the end of 2012, a total of 9,361 shareholders were enrolled in this program. Beginning in 2013, Novartis will continue to offer this program only for Swiss residents.

Novartis previously offered US investors an ADS Direct Share Purchase Plan. Novartis has terminated this Plan. JPMorgan will offer a similar program to US investors.

#### Liquidity/Short-term Funding 2012 and 2011

We continuously track our liquidity position and asset/liability profile. This involves modeling cash flow maturity profiles based on both historical experiences and contractual expectations to project our liquidity requirements. We seek to preserve prudent liquidity and funding capabilities.

We are not aware of significant demands to change our level of liquidity needed to support normal business activity. We intend to use part of our free cash flow to reduce our financial debt. We make use of various borrowing facilities provided by several financial institutions. We also successfully issued various bonds in 2010 and 2012. In addition, we raised funds through our commercial paper programs. We have no commitments from repurchase or securities lending transactions. The principal reason for the decrease in average current financial debt in 2012 compared to 2011 is the decrease in commercial paper during 2012.

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An overview of the movements in our current financial debt and related interest rates is set forth below:

	December 31	Average interest rate at year end	Average balance during the year	Average interest rate during the year	Maximum balance during the year
	\$ m	%	\$ m	%	\$ m
2012	·				
Interest-bearing accounts of associates	1,541	1.03	1,490	1.06	1,554
Other bank and financial debt	1,270	3.99	1,662	3.05	2,049
Commercial paper	963	0.66	3,738	0.17	6,287
Current portion of non-current financial					
debt	2,009	na	1,597	na	2,009
Fair value of derivative financial					
instruments	162	na	102	na	219
Total current financial debt	5,945		8,589		12,118
2011					
Interest-bearing accounts of associates	1,357	1.36	1,463	1.25	1,626
Other bank and financial debt	2,053	3.38	3,784	1.83	7,749
Commercial paper	2,156	0.55	5,597	0.21	8,673
Current portion of non-current financial debt	778	na	479	na	911
Fair value of derivative financial	20		07		104
instruments	30	na	97	na	184
Total current financial debt	6,374		11,420		19,143

na

Interest bearing accounts of associates relate to employee deposits in CHF from the compensation of associates employed by Swiss entities (actual interest rate: 1%). Other bank and financial debt refer to usual lending and overdraft facilities.

### 5.C Research & Development, Patents and Licenses

Our R&D spending totaled \$9.3 billion, \$9.6 billion and \$9.1 billion (\$9.1 billion, \$9.2 billion and \$8.1 billion excluding impairments and amortization charges) for the years 2012, 2011 and 2010, respectively. Each of our divisions has its own R&D and patents policies. Our divisions have numerous products in various stages of development. For further information on these policies and these products in development, see "Item 4. Information on the Company 4.B Business Overview."

As described in the "Risk Factors" section and elsewhere in this Form 20-F, our drug development efforts are subject to the risks and uncertainties inherent in any new drug development program. Due to the risks and uncertainties involved in progressing through pre-clinical development and clinical trials, and the time and cost involved in obtaining regulatory approvals, among other factors, we cannot reasonably estimate the timing, completion dates, and costs, or range of costs, of our drug development program, or of the development of any particular development compound, see "Item 3. Key Information 3.D Risk Factors." In addition, for a description of the research and development process for the development of

<sup>=</sup> not applicable or available

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new drugs and our other products, and the regulatory process for their approval, see "Item 4. Information on the Company 4.B Business Overview."

#### **5.D Trend Information**

Please see " 5.A Operating Results Factors Affecting Results of Operations" and "Item 4, Information on the Company 4.B Business Overview" for trend information.

### **5.E Off-Balance Sheet Arrangements**

We have no unconsolidated special purpose financing or partnership entities or other off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, that is material to investors.

### **5.F Aggregate Contractual Obligations**

The following table summarizes our contractual obligations and other commercial commitments at December 31, 2012 and the effect such obligations and commitments are expected to have on our liquidity and cash flow in future periods:

	Payments due by period				
	Less than				After
	Total	1 year	2-3 years	4-5 years	5 years
	\$ m	\$ m	\$ m	\$ m	\$ m
Non-current financial debt	15,790	2,009	5,823	2,006	5,952
Operating leases	3,145	372	467	293	2,013
Unfunded pensions and other post-retirement obligations	2,144	97	195	207	1,645
Research & Development					
Unconditional commitments	219	48	79	59	33
Potential milestone commitments	2,014	456	526	766	266
Purchase commitments					
Property, plant & equipment	755	508	236	11	
Total contractual cash obligations	24,067	3,490	7,326	3,342	9,909

The Group intends to fund the R&D and purchase commitments with internally generated resources.

For other contingencies, see "Item 4. Information on the Company 4.D Property, Plants and Equipment Environmental Matters", "Item 8. Financial Information 8.A Consolidated Statements and Other Financial Information" and "Item 18. Financial Statements" note 20".

#### Item 6. Directors, Senior Management and Employees

### Item 6.A Directors and Senior Management

#### **Board of Directors**

Daniel Vasella, M.D., Swiss, age 59

**Function at Novartis AG** Daniel Vasella, M.D., is Chairman of the Board of Directors for Novartis AG. He served as Chief Executive Officer (CEO) and executive member of the Board of Directors for 14 years following the merger that created Novartis in 1996. Dr. Vasella was appointed Chairman in April 1999.

Other activities Dr. Vasella is a member of the boards of directors of US-based PepsiCo Inc. and American Express Co. He is also a member of the International Board of Governors of the Peres Center for Peace in Israel, the International Business Leaders Advisory Council for the Mayor of Shanghai, and is a foreign honorary member of the American Academy of Arts and Sciences. He further is a member of the board of trustees of the Carnegie Endowment for International Peace. In addition, Dr. Vasella serves as a member of several industry associations and educational institutions.

**Professional background** Before the Novartis merger, Dr. Vasella was CEO of Sandoz Pharma Ltd. and a member of the Sandoz Group Executive Committee. From 1988 to 1992, he was with Sandoz Pharmaceuticals Corporation in the United States, prior to which he held a number of medical positions in Switzerland. He graduated with an M.D. from the University of Bern in Switzerland and completed executive training at the Harvard Business School in the United States. He also was awarded an honorary doctorate by the University of Basel, Switzerland.

**Key knowledge/experience** *Leadership, Biomedical Science and Global Marketing experience* former CEO of Novartis; advisory panel member for international organizations. *Industry experience* board member for global consumer goods company and global financial services company.

### Ulrich Lehner, Ph.D., German, age 66

**Function at Novartis AG** Ulrich Lehner, Ph.D., has been a member of the Board of Directors since 2002. He qualifies as an independent Non-Executive Director. He serves as Vice Chairman, and Chairman of the Corporate Governance and Nomination Committee. He is also a member of the Audit and Compliance Committee, the Risk Committee, the Chairman's Committee, and the Compensation Committee. The Board of Directors has appointed him as Audit Committee Financial Expert.

Other activities Mr. Lehner is a member of the shareholders' committee of Henkel AG & Co. KGaA, chairman of the supervisory board of Deutsche Telekom AG, and serves as a member of the supervisory boards of E.ON AG, ThyssenKrupp AG, Porsche Automobil Holding SE and Henkel Management AG, all in Germany. He is also a member of the shareholders' committee of Dr. August Oetker KG and Krombacher Brauerei, both in Germany.

**Professional background** Mr. Lehner graduated in business administration and mechanical engineering from the Darmstadt University of Technology, Germany, in 1975. From 1975 to 1981, he was an auditor with KPMG Deutsche Treuhand-Gesellschaft AG in Duesseldorf. In 1981, he joined Henkel KGaA. After heading the controlling department of Fried. Krupp GmbH in Germany from 1983 to 1986, Mr. Lehner returned to Henkel as finance director. From 1991 to 1994, he headed Henkel Asia-Pacific Ltd. in Hong Kong, and from 1995 to 2000, he served as executive vice president, finance/logistics, of Henkel KGaA. From 2000 to 2008, Mr. Lehner served as chairman of the management board of Henkel KGaA.

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**Key knowledge/experience** *Leadership and Global experience* chairman of supervisory board of global telecommunication company; former chairman of the management board of global consumer goods company. *Industry experience* member of supervisory boards of global energy, automotive and manufacturing technology companies.

#### Dimitri Azar, M.D., American, age 53

**Function at Novartis AG** Dimitri Azar, M.D., has been a member of the Board of Directors since February 2012. He qualifies as an independent Non-Executive Director.

Other activities Dr. Azar is dean of the College of Medicine and professor of ophthalmology, bioengineering and pharmacology at the University of Illinois at Chicago in the United States, where he formerly was head of the Department of Ophthalmology and Visual Sciences. He sits on the board of trustees of the Chicago Ophthalmological Society and the Association of Research in Vision and Ophthalmology. Dr. Azar is a member of the American Ophthalmological Society and holds multiple committee positions with the American Academy of Ophthalmology.

**Professional background** Dr. Azar began his career at the American University Medical Center, Beirut, Lebanon, and completed his fellowship and residency training at the Massachusetts Eye and Ear Infirmary at Harvard Medical School in the United States. His research on matrix-metalloproteinases in corneal wound healing and angiogenesis has been funded by the National Institutes of Health since 1993. Dr. Azar practiced at the Wilmer Ophthalmologic Institute at The Johns Hopkins Hospital School of Medicine, then returned to the Massachusetts Eye and Ear Infirmary as director of the cornea and external disease. He became professor of ophthalmology with tenure at Harvard Medical School in 2003. Dr. Azar holds an Executive Master of Business Administration from the University of Chicago, Booth School of Business.

**Key knowledge/experience** *Leadership, Healthcare and Education experience* dean and professor of leading US university medical school. *Biomedical Science experience* federally funded clinician-scientist and research fellowship recipient.

#### William Brody, M.D., Ph.D., American, age 68

**Function at Novartis AG** William Brody, M.D., Ph.D., has been a member of the Board of Directors since 2009. He qualifies as an independent Non-Executive Director. He is a member of the Compensation Committee.

Other activities Dr. Brody is president of the Salk Institute for Biological Studies, La Jolla, California, United States. He is also a member of the boards of directors of the US-based International Business Machines Corp. and Kool Smiles Inc., and the mutual funds boards of T. Rowe Price. He is a member of numerous professional associations, and also serves on the advisory boards of various government and nonprofit organizations.

**Professional background** Dr. Brody earned his bachelor's and master's degrees in electrical engineering from the Massachusetts Institute of Technology before completing his M.D. and Ph.D. at Stanford University, all in the United States. Following training in cardiovascular surgery and radiology he held various academic positions, including professor for radiology and electrical engineering at Stanford University, and director of the department of radiology at The Johns Hopkins University. From 1996 to 2009, he was president of The Johns Hopkins University, and since 2009, president of the Salk Institute for Biological Studies in the United States. He is a member of the US National Academy of Engineering and the Institute of Medicine.

**Key knowledge/experience** *Leadership, Biomedical Science, Healthcare and Education experience* president of leading US scientific research institution; former president of leading US university. *Global, Engineering and Technology experience* former board member of global technology company.

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#### Srikant Datar, Ph.D., American, age 59

**Function at Novartis AG** Srikant Datar, Ph.D., has been a member of the Board of Directors since 2003. He qualifies as an independent Non-Executive Director. He is Chairman of the Audit and Compliance Committee, and a member of the Chairman's Committee, the Risk Committee and the Compensation Committee. The Board of Directors has appointed him as Audit Committee Financial Expert.

Other activities Mr. Datar is Arthur Lowes Dickinson Professor at the Graduate School of Business Administration at Harvard University. He is also a member of the boards of directors of ICF International Inc. and Stryker Corp., both in the United States, and of HCL Technologies in India.

**Professional background** Mr. Datar graduated with distinction in mathematics and economics from the University of Bombay, India, in 1973. He is a Chartered Accountant, and holds two master's degrees and a doctorate from Stanford University. Mr. Datar has worked as an accountant and planner in industry, and as a professor at Carnegie Mellon University, Stanford University and Harvard University, all in the United States. His research interests are in the areas of cost management, measurement of productivity, new product development, time-based competition, incentives, and performance evaluation. He is the author of many scientific publications, and has received several academic awards and honors. Mr. Datar has advised and worked with numerous companies in research, development and training.

**Key knowledge/experience** Leadership and Education experience former senior associate dean and current professor of leading US university. Global and Industry experience board member of global professional services firm; board member of global leading medical technology company; board member of Indian high-tech company.

#### Ann Fudge, American, age 61

**Function at Novartis AG** Ann Fudge has been a member of the Board of Directors since 2008. She qualifies as an independent Non-Executive Director. She is a member of the Corporate Governance and Nomination Committee, and the Risk Committee.

Other activities Ms. Fudge serves on the boards of directors of General Electric Co. in the United States; Unilever NV, London and Rotterdam, Netherlands; and Infosys Ltd., India. She is a trustee of the New York-based Rockefeller Foundation, and is chairman of the US Programs Advisory Panel of the Bill & Melinda Gates Foundation. Ms. Fudge is further a member of the Harvard University Corporation Committee on Finance. She is also on the board of the Council on Foreign Relations.

**Professional background** Ms. Fudge received her bachelor's degree from Simmons College and her Masters of Business Administration from Harvard University Graduate School of Business in the United States. She is former chairman and CEO of Young & Rubicam Brands, New York. Before that, she served as president of the Beverages, Desserts and Post Division of Kraft Foods Inc., Northfield, Illinois.

**Key knowledge/experience** *Leadership and Marketing experience* former chairman and CEO of global marketing communications company; former president of leading consumer products business unit. *Global and Industry experience* board member of global technology company and global consumer goods company.

#### Pierre Landolt, Ph.D., Swiss, age 65

**Function at Novartis AG** Pierre Landolt, Ph.D., has been a member of the Board of Directors since 1996. He qualifies as an independent Non-Executive Director. He is a member of the Corporate Governance and Nomination Committee.

Other activities Mr. Landolt is currently chairman of the Sandoz Family Foundation and oversees the development of the foundation in several investment fields. He is also a partner with unlimited liabilities

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of the Swiss private bank Landolt & Cie. In Switzerland, he is chairman of Emasan AG and Vaucher Manufacture Fleurier SA, and vice chairman of Parmigiani Fleurier SA. He is a member of the board of EcoCarbone SAS, France, and Amazentis SA, Switzerland. He is also vice chairman of the Montreux Jazz Festival Foundation. In Brazil, Mr. Landolt serves as president of the Instituto Fazenda Tamanduá, the Instituto Estrela de Fomento ao Microcrédito, AxialPar Ltda. and Moco Agropecuaria Ltda.

**Professional background** Mr. Landolt graduated with a bachelor's degree in law from the University of Paris Assas. From 1974 to 1976 he worked for Sandoz Brazil. In 1977 he acquired an agricultural estate in the semi-arid Northeast Region of Brazil, and over several years converted it into a model farm in organic and biodynamic production. Since 1997 Mr. Landolt has been associate and chairman of AxialPar Ltda, Brazil, an investment company focused on sustainable development. In 2000 he co-founded EcoCarbone SAS, a company active in the design and development of carbon-sequestration processes. In 2007 he co-founded Amazentis SA, a startup company active in the convergence space of medication and nutrition.

**Key knowledge/experience** *Banking and Industry experience; International and Emerging Market experience* partner of private bank; chairman and vice chairman of luxury goods companies. *Leadership and Global experience* President of large family investment holding; board member of global agribusiness company.

#### Enrico Vanni, Ph.D., Swiss, age 61

**Function at Novartis AG** Enrico Vanni, Ph.D., has been a member of the Board of Directors since 2011. He qualifies as an independent Non-Executive Director. He is Chairman of the Compensation Committee, and a member of the Audit and Compliance Committee.

Other activities Since his retirement as director of McKinsey & Company in 2007, Mr. Vanni has been an independent consultant. He is currently a member of several boards of directors, in industries from healthcare to private banking, for nonlisted companies including Eclosion2, Denzler & Partners SA and Banque Privée BCP (Suisse) SA, all based in Switzerland.

**Professional background** Mr. Vanni holds an engineering degree in chemistry from the Federal Polytechnic School of Lausanne, Switzerland, a Ph.D. in chemistry from the University of Lausanne, as well as a Master of Business Administration from INSEAD in Fontainebleau, France. He began his career as a research engineer at International Business Machines Corp. in California, United States, and joined McKinsey & Company in Zurich in 1980. He managed the Geneva office for McKinsey from 1988 to 2004, and consulted for companies in the pharmaceutical, consumer and finance sectors. He led McKinsey's European pharmaceutical practice and served as member of the partner review committee of the firm prior to his retirement in 2007. As an independent consultant, Mr. Vanni has continued to support leaders of pharmaceutical and biotechnology companies on core strategic challengesfacing the healthcare industry.

**Key knowledge/experience** *Global industry experience* senior consultant of global pharmaceutical/biotech companies, consumer goods and financial institutions. *Science experience* research engineer in technology company and management of projects in global pharmaceutical R&D. *Leadership experience* office management of global consultant company and leadership of its European pharmaceutical practice.

### Andreas von Planta, Ph.D., Swiss, age 57

**Function at Novartis AG** Andreas von Planta, Ph.D., has been a member of the Board of Directors since 2006. He qualifies as an independent Non-Executive Director. He is Chairman of the Risk Committee, and is a member of the Audit and Compliance Committee as well as the Corporate Governance and Nomination Committee.

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Other activities Mr. von Planta is chairman of the Schweizerische National-Versicherungs-Gesellschaft AG and a board member of Holcim Ltd., both in Switzerland. He is also a board member of various Swiss subsidiaries of foreign companies and other nonlisted Swiss companies. He is a member of the Board of Editors of the "Swiss Review of Business Law" and is a former chairman of the Geneva Association of Business Law. Mr. von Planta is chairman of the regulatory board of the SIX Swiss Exchange AG.

**Professional background** Mr. von Planta holds lic. iur. and Ph.D. degrees from the University of Basel, Switzerland, and an LL.M. from Columbia University School of Law, New York, United States. He passed his bar examinations in Basel in 1982. Since 1983 he has lived in Geneva and worked for the law firm Lenz & Staehelin, where he became a partner in 1988. His areas of specialization include corporate law, corporate governance, corporate finance, company reorganizations, and mergers and acquisitions.

**Key knowledge/experience** *Leadership and Global experience* chairman of insurance company; board member of global construction materials manufacturer. *Industry experience* partner of leading Swiss law firm.

#### Dr. Ing. Wendelin Wiedeking, German, age 60

**Function at Novartis AG** Dr. Ing. Wendelin Wiedeking has been a member of the Board of Directors since 2003. He qualifies as an independent Non-Executive Director. He is a member of the Audit and Compliance Committee and of the Risk Committee.

Other activities Mr. Wiedeking was chairman of the executive board of Porsche Automobil Holding SE and of Dr. Ing. h.c. F. Porsche AG, both in Germany, until July 2009. Since then he has been an entrepreneur.

**Professional background** Mr. Wiedeking graduated in mechanical engineering in 1978 and worked as a scientific assistant in the machine tool laboratory of the Rhine-Westphalian College of Advanced Technology in Germany. His professional career began in 1983 in Germany as director's assistant in the production and materials management area of Dr. Ing. h.c. F. Porsche AG in Stuttgart-Zuffenhausen. In 1988, he moved to Glyco Metall-Werke KG in Wiesbaden as division manager, where he advanced by 1990 to the position of CEO and chairman of the board of management of Glyco AG. In 1991, he returned to Dr. Ing. h.c. F. Porsche AG as production director. A year later, the supervisory board appointed him spokesman of the executive board (CEO), then chairman in 1993.

**Key knowledge/experience** *Leadership, Global and Industry experience* former chairman and CEO of global automotive company. *Engineering and Technology experience* former chairman and CEO of manufacturing supply company.

# Marjorie Mun Tak Yang, Chinese, age 60

**Function at Novartis AG** Marjorie Mun Tak Yang has been a member of the Board of Directors since 2008. She qualifies as an independent Non-Executive Director. She is a member of the Compensation Committee.

Other activities Ms. Yang is chairman of the Esquel Group, Hong Kong, China. She is a member of the Executive Council of the Hong Kong Special Administrative Region. In China, she is a member of the National Committee of the Chinese People's Political Consultative Conference. She currently serves on the boards of Swire Pacific Ltd., and The Hong Kong and Shanghai Banking Corp. Ltd. in Hong Kong, and on the boards of a number of nonlisted companies. In January 2010 she was appointed as Chairman of the Council of the Hong Kong Polytechnic University. She also serves on the advisory boards of Harvard Business School, and Tsinghua School of Economics and Management, in the United States and China, respectively. From 2001 to 2011, Ms. Yang was a member of the MIT Corporation.

**Professional background** Ms. Yang graduated with a bachelor's degree in mathematics from Massachusetts Institute of Technology and holds a master's degree from Harvard Business School, both in

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the United States. From 1976 to 1978, she was an associate in Corporate Finance, Mergers and Acquisitions, with the First Boston Corp. in New York, United States. In 1979, she returned to Hong Kong and became a founding member of Esquel Group. She was appointed chairman of the Group in 1995.

**Key knowledge/experience** *Leadership, Global and Industry experience* chairman of global textile manufacturing company *Education and Science experience* trustee of leading US research university; leadership roles at multiple universities.

### Rolf M. Zinkernagel, M.D., Swiss, age 68

**Function at Novartis AG** Rolf M. Zinkernagel, M.D., has been a member of the Board of Directors since 1999. He qualifies as an independent Non-Executive Director. He is a member of the Corporate Governance and Nomination Committee.

Other activities Dr. Zinkernagel was vice president of the International Union of Immunological Societies until 2010. He is a member of the scientific advisory boards of Bio-Alliance AG, Germany; Aravis General Partner Ltd., Cayman Islands and Switzerland; Telormedix, Switzerland; X-Biotech, Canada; Novimmune, Switzerland; Cancevir, Switzerland; MannKind, United States; and the Biomedical Sciences International Advisory Council, Singapore. Dr. Zinkernagel is also a science consultant to Chilka Ltd., Cayman Islands; Ganymed, Germany; and Zhen-Ao Group, China.

**Professional background** Dr. Zinkernagel graduated from the University of Basel, Switzerland, with an M.D. in 1970. From 1992 to 2008, he was a professor and director of the Institute of Experimental Immunology at the University of Zurich, and after retirement in 2008 continues to be active at the University of Zurich. Dr. Zinkernagel has received many awards and prizes for his work and contribution to science, notably the Nobel Prize in medicine, which he was awarded in 1996.

**Key knowledge/experience** *Biomedical Science and Education experience* former professor and director at leading Swiss university. *Leadership and Global experience* member of scientific advisory boards of numerous global biotech companies; member of major international research councils.

### **Executive Committee**

### Joseph Jimenez, American, age 53

Joseph Jimenez has been Chief Executive Officer (CEO) of Novartis since 2010. Mr. Jimenez is responsible for leading the company's diversified healthcare portfolio of leading businesses in innovative pharmaceuticals, eye care, generics, vaccines and diagnostics, and OTC and animal health. Previously Mr. Jimenez served as Division Head, Novartis Pharmaceuticals. He led the transformation of the pharmaceutical portfolio to balance mass market and specialty products, and significantly increased the percentage of sales from newly launched products. Mr. Jimenez also worked to realign the division's commercial approach to focus on the individual needs of customers, and incorporated more technological tools to better connect with patients and customers. Mr. Jimenez joined Novartis in April 2007 as Division Head, Novartis Consumer Health. Previously, he served as president and CEO of the North America business for the H.J. Heinz Co., and as president and CEO of Heinz in Europe from 2002 to 2006. Prior to joining Novartis, he was a nonexecutive director of AstraZeneca PLC, United Kingdom, from 2002 to 2007. He was also an adviser for the private equity organization Blackstone Group in the United States. Mr. Jimenez is a member of the board of directors of Colgate-Palmolive Co., New York. He graduated in 1982 with a bachelor's degree from Stanford University and in 1984 with a Master of Business Administration from the University of California, Berkeley.

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### Juergen Brokatzky-Geiger, Ph.D., German, age 60

Juergen Brokatzky-Geiger, Ph.D., has been Head of Human Resources of Novartis since 2003. He is a member of the Executive Committee of Novartis. Mr. Brokatzky-Geiger joined Ciba-Geigy Ltd. in 1983 as a Ph.D. chemist in the Pharmaceuticals Division in Switzerland. After a job rotation in the United States, he held positions of increasing responsibility in Research and Development (R&D), including Group Leader of Process R&D, Head of Process R&D, and Head of Process Development and Pilot Plant Operations. During the merger of Ciba-Geigy and Sandoz in 1996, Mr. Brokatzky-Geiger was appointed Integration Officer of Technical Operations. He later became the Head of Chemical and Analytical Development, and served as the Global Head of Technical R&D from 1999 to 2003. Mr. Brokatzky-Geiger is a member of the board of Bachem AG in Switzerland. He graduated with a Ph.D. in chemistry from the University of Freiburg, Germany, in 1982.

#### Kevin Buehler, American, age 55

Kevin Buehler has been Division Head, Alcon, since 2011. He is a member of the Executive Committee of Novartis. Mr. Buehler was president and CEO of Alcon Inc. from 2009 to 2011. He began his career with Alcon in 1984 as a regional sales manager in the Consumer Products Division, and held positions of increasing responsibility before being named director of sales and marketing. In 1996, he became director of Alcon's US Managed Care and Falcon Generic Pharmaceutical groups, and became vice president in 1998. The following year he returned to the US Consumer Products Division as vice president and general manager. Mr. Buehler moved to the International Division in 2002 as vice president and regional manager, Latin America and Caribbean. He was later named area vice president, Latin America, Canada, Australia and Far East. Mr. Buehler also served as senior vice president, global markets, and chief marketing officer. Prior to joining Alcon, he worked for The Gillette Co. and Snyder Drug Stores, both in the United States. Mr. Buehler holds a bachelor's degree from Carroll University in Waukesha, Wisconsin, in the United States, with concentrations in business administration and political science. He completed the Harvard Program for Management Development in 1993.

### Felix R. Ehrat, Ph.D., Swiss, age 55

Felix R. Ehrat, Ph.D., has been Group General Counsel since October 2011. He is a member of the Executive Committee of Novartis. Mr. Ehrat is a leading practitioner of corporate, banking, and mergers and acquisitions law, as well as an expert in corporate governance and arbitration. He started his career as an associate with Baer & Karrer Ltd. in Zurich in 1987, became partner in 1992, and advanced to senior partner (2003 to 2011) and executive chairman of the board (2007 to 2011) of the firm. Mr. Ehrat is chairman of Globalance Bank AG in Switzerland, and board member of several organizations in the cultural field. Previously, Mr. Ehrat was, among other things, chairman of Banca del Gottardo, and a board member of Julius Baer Holding AG, Austriamicrosystems AG, Charles Voegele Holding AG and Carlo Gavazzi Holding AG. Mr. Ehrat was admitted to the Zurich bar in 1985 and received his doctorate of law from the University of Zurich in 1990. In 1986, he completed an LL.M. at McGeorge School of Law in the United States. His past memberships and positions include: the International Bar Association, where he was co-chair of the Committee on Corporate and M&A Law from 2007 to 2008; Association Internationale des Jeunes Avocats, where he was president from 1998 to 1999; and the Swiss Arbitration Association, the Zurich Bar Association, and the Swiss Bar Association.

### David Epstein, American, age 51

David Epstein has been Division Head, Novartis Pharmaceuticals, since 2010. He is a member of the Executive Committee of Novartis. Prior to his current appointment, Mr. Epstein served as Head of Novartis Oncology for nearly 10 years. In addition, Mr. Epstein has led the Molecular Diagnostics Unit since its creation in 2008. Before joining Novartis, Mr. Epstein was an associate in the strategy practice of the consulting firm Booz Allen Hamilton Inc. in the United States. Mr. Epstein joined Sandoz, a

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predecessor company of Novartis, in 1989, and held various leadership positions of increasing responsibility for the company, including Chief Operating Officer of Novartis Pharmaceuticals Corporation in the United States and Head of Novartis Specialty Medicines. Mr. Epstein graduated with a bachelor's degree in pharmacy from The Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, in 1984, and with a Master of Business Administration in finance and marketing from New York's Columbia University Graduate School of Business in 1987.

#### Mark C. Fishman, M.D., American, age 61

Mark C. Fishman, M.D., has been President of the Novartis Institutes for BioMedical Research (NIBR) since 2002. He is a member of the Executive Committee of Novartis. Before joining Novartis in 2002, Dr. Fishman was chief of cardiology and director of the Cardiovascular Research Center at Massachusetts General Hospital, and was professor of medicine at Harvard Medical School, both in the United States. Dr. Fishman completed his internal medicine residency, chief residency and cardiology training at Massachusetts General Hospital. Dr. Fishman graduated with a bachelor's degree from Yale College in 1972 and an M.D. from Harvard Medical School in 1976. He has been honored with many awards and distinguished lectureships, and is a member of the Institute of Medicine of the National Academies and a Fellow of the American Academy of Arts and Sciences, both in the United States.

### Jeff George, American, age 39

Jeff George has been Division Head, Sandoz, since 2008. He is a member of the Executive Committee of Novartis. Mr. George joined the Vaccines and Diagnostics Division of Novartis in 2007 as Head of Commercial Operations for Western and Eastern Europe. He then advanced to Head of Emerging Markets for the Middle East, Africa, Southeast Asia and CIS at Novartis Pharmaceuticals. Before joining Novartis, Mr. George was a Senior Director of Strategy and Business Development at Gap Inc., San Francisco, United States. From 2001 to 2004, he was an Engagement Manager with McKinsey & Company, also in San Francisco. Mr. George received a Master of Business Administration from Harvard University in 2001. He graduated in 1999 with a master's degree from The Johns Hopkins University's School of Advanced International Studies, where he studied international economics and emerging markets political economy. In 1996, he received his bachelor's degree in international relations from Carleton College in Northfield, Minnesota, in the United States.

### George Gunn, MRCVS, British, age 62

George Gunn has been Division Head, Novartis Animal Health, and Head, Corporate Responsibility, since 2011. He is a member of the Executive Committee of Novartis. Before joining Novartis, Mr. Gunn was president of Pharmacia Animal Health, based in the United States. Previously, he spent more than 15 years in positions of increasing responsibility in healthcare companies. He worked as a veterinary surgeon for nine years before entering the industry. Mr. Gunn joined Novartis in 2003 as Head of Novartis Animal Health, North America. In 2004, he assumed his position as Head of the Animal Health Business Unit. In addition to this role, he was Division Head, Novartis Consumer Health, from 2008 to 2011. Mr. Gunn graduated with a bachelor of veterinary medicine and surgery degree from the Royal (Dick) School of Veterinary Studies in the United Kingdom in 1973. He graduated with a diploma in veterinary state medicine from the same school in 1978. In 2008, he received an honorary doctorate in veterinary medicine and surgery from the University of Edinburgh, Scotland.

### Brian McNamara, American, age 46

Brian McNamara has been Division Head, Novartis OTC and a permanent attendee of the Executive Committee of Novartis since February 2012. As of January 1, 2013, he is a member of the Executive Committee of Novartis. Prior to this role, Mr. McNamara served as President, Americas Region, for Novartis OTC. Since joining Novartis OTC in 2004 as Senior Vice President and General Manager of

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Novartis OTC North America, Mr. McNamara has worked on a number of strategic initiatives. Mr. McNamara also served as President of Novartis OTC Europe from 2007 until 2010. Mr. McNamara began his career at Procter & Gamble Co., Cincinnati, United States, where he gained extensive experience in consumer and brand marketing, product supply, and customer leadership. Mr. McNamara has served on the board of directors and the executive committee of the Consumer Healthcare Products Association in the United States. He is also a former board member of the Association of the European Self-Medication Industry and chairman of its economic affairs committee. Mr. McNamara received a Master of Business Administration in Finance from the University of Cincinnati and a bachelor's degree in electrical engineering from Union College, both in the United States.

#### Andrin Oswald, M.D., Swiss, age 41

Andrin Oswald, M.D., has been Division Head, Novartis Vaccines and Diagnostics, since 2008. He is a member of the Executive Committee of Novartis. Previously, Dr. Oswald was CEO of Speedel Holding AG and Global Head of Pharmaceutical Development Franchises in the Novartis Pharmaceuticals Division, both in Switzerland. Dr. Oswald joined Novartis in 2005 as Assistant to the Chairman and CEO. Before his appointment as Head of Development Franchises, he served as Head of the Country Pharmaceuticals Organization (CPO) and Country President for Novartis in South Korea. Dr. Oswald joined Novartis from McKinsey & Company, Switzerland, where he was an associate principal. Between 2002 and 2003, he was a delegate of the International Committee of the Red Cross (ICRC) to Nepal. He holds a doctorate in medicine from the University of Geneva.

#### Jonathan Symonds, British, age 53

Jonathan Symonds has been Chief Financial Officer (CFO) of Novartis since 2010. He is a member of the Executive Committee of Novartis. Before joining Novartis in 2009, Mr. Symonds was partner and managing director of Goldman Sachs Group Inc. in the United Kingdom. He also has eight years of experience as CFO of AstraZeneca PLC, and previously held positions as Group Finance Director at Zeneca and partner at KPMG. From 2004 to 2007, Mr. Symonds was a director of Diageo PLC and chairman of the audit committee. Other previous roles include director and audit committee chairman of Qinetiq PLC, chairman of the 100 Group of Finance Directors, joint chairman of the Business Tax Forum, board member of the Accounting Standards Board, and founder of the Oxford University Centre for Business Taxation Research, all in the United Kingdom. Mr. Symonds graduated with a first-class degree in business finance from the University of Hertfordshire, United Kingdom, in 1980, and became a Fellow of Chartered Accountants in 1982. He is a Commander of the British Empire (CBE).

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### Item 6.B Compensation

Novartis aspires to be an employer of choice and to attract and retain best-in-class talent around the world.

Our compensation plans are designed to support our position as a preeminent global healthcare company. They provide competitive compensation and benefits for world-class talent in a competitive market. They are aligned with our business performance objectives that are key to our sustained success while being transparent, coherent and consistent with our pay-for-performance philosophy. Our compensation system aims to encourage innovation and entrepreneurship and, at the same time, deter excessive risk-taking at the expense of the long-term condition of the Group.

The Compensation Report describes our compensation system and philosophy, and provides details on the compensation related to 2012 performance.

#### MANAGEMENT SUMMARY

### Stakeholders outreach and engagement

Novartis compensation policies and practices aim to create long-term value for the Group through its talented and dedicated associates.

Our Board and management reach out regularly to our stakeholders to gather feedback on our compensation system. This includes telephone and in-person discussions with individual and institutional investors and proxy advisors. In addition, we answer and take into consideration all written queries and comments. We regularly analyze market practices and take advice from the Compensation Committee's independent advisors.

With the benefit of this feedback, in 2012, the Compensation Committee undertook a strategic review of our compensation system, and is proposing several fundamental changes to the compensation structure for the CEO and the members of the Executive Committee from 2014 onwards. These changes have been approved by the Board and will be submitted to a consultative shareholder vote at the Annual General Meeting in 2013. Further details of the proposed changes are set out in a separate summary attached to the Notice of Annual General Meeting 2013.

In addition, based on the Compensation Committee's annual review of our compensation system, in 2012, we have decided with immediate effect to:

Increase our level of disclosure regarding performance, in particular, for the CEO against his 2012 objectives.

Further pursue the shift from the Equity Plan "Select" (our time-vesting long-term incentive program) to the Long-Term Performance Plan "LTPP" (our performance-vesting long-term incentive program) for members of the Executive Committee.

Exclude the CEO and the members of the Executive Committee from receiving Special Share Awards that are granted on a discretionary basis and are not contingent on the achievement of future targets.

#### Novartis Performance in 2012 and CEO Compensation

In 2012, overall net sales for the Group were maintained in line with the prior year in constant currencies (cc), despite global economic challenges and the loss of our exclusivity of *Diovan*. Core operating income was slightly below the prior year in cc. Strong new product launches helped rejuvenate our portfolio. Recently launched products accounted for 29% of Group net sales, including *Gilenya*, *Tasigna*, *Lucentis* and *Afinitor* in our Pharmaceuticals Division. Growth in emerging markets (i.e. 6% on average) contributed \$13.8 billion to Group net sales.

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The Pharmaceuticals Division exceeded its net sales goals and significantly surpassed its operating income targets, while Alcon, Sandoz and Animal Health performed in line with financial targets. Our OTC business and Vaccines and Diagnostics Division were below target, as both were impacted by quality issues and production bottlenecks.

The company continued to focus on driving growth through science-based innovation, which helped us maintain one of the industry's strongest pipelines: our Pharmaceutical R&D projects include 71 new compounds, which is among the highest in the industry. Sandoz had 12 first-to-files and further expanded its lead in differentiated products including biosimilars and dermatology. The Vaccines and Diagnostics Division received a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) *Bexsero* our groundbreaking meningococcal disease vaccine.

The company took significant measures to improve production quality. Quality issues at a US production site affected the performance of OTC and Animal Health, which together make up our Consumer Health Division. Both businesses are expected to return to growth in 2013 amid continued improvement measures.

Overall, the company delivered solid financial results and, for the 16<sup>th</sup> consecutive year, we propose to raise the annual dividend. Adding the share price appreciation to the dividend, we delivered a total shareholder return of 11.8% in CHF (and 15% in US dollars for ADS holders) over 2012.

The Board of Directors assessed that, under the CEO's leadership and with its strong pipeline of innovative products, the company is strategically well-positioned to operate successfully in the evolving healthcare industry.

The Board of Directors determined that the CEO met most of the objectives that were set at the start of the year in challenging market conditions and fully acknowledged the breakthroughs in innovation and the efficiency gains. For more details on the 2012 CEO performance, see "2012 CEO performance" below.

Based on the assessment of both the company and individual performance, the Compensation Committee determined that the CEO earned an annual incentive payout of CHF 1.4 million and long-term incentive "Select" of CHF 4.8 million. In addition, based on the achievement of Novartis Economic Value Added over the last three years, the CEO earned 76,937 shares, representing a value of CHF 4.7 million. The CEO's total compensation for 2012 (i.e. base salary, variable compensation, pension and other benefits) was CHF 13.2 million. This represents a total reduction of 15.9% from 2011, or 9.8% excluding the value of the 2011 LSSP match (our leveraged share savings plan). The Compensation Committee determined that this was appropriate, given that the company's overall performance in 2012 was lower in certain areas than in 2011.

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The CEO's total compensation for 2012 is set out in the table below.
It is important to note that not all of the 2012 compensation is finally acquired. A significant portion is deferred and prospectively payable at a future date subject to performance at the end of the performance cycle and employment conditions. If the CEO leaves Novartis for reasons other than retirement, disability or death, his unvested long-term incentive compensation is forfeited, even in case of termination without cause. The chart below sets out the portion acquired immediately ("realized") and the portion deferred and prospectively payable at a future date ("unrealized").
The Compensation Committee has determined that the CEO's annual base salary for 2013 is increased by 1.5% from 2012, in line with
general salary increases for other Swiss associates.
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#### Key features of our 2012 compensation system for the CEO and the members of the Executive Committee

### Pay-for-performance

Compensation of executives is strongly linked to our performance. Our compensation programs are designed to pay our executives relative to Novartis performance, measured against stretched financial goals, individual performance and behavior, as well as share performance.

#### Competitive compensation

Regular benchmarking ensures that compensation opportunities offered to executives enable Novartis to attract and retain top talent. Generally, Novartis compensation programs aim at compensating associates at the median level of compensation, with upper quartile (>75<sup>th</sup> percentile) for sustained superior performance.

### Equity ownership

To align the interests of our management with our shareholders, we require our CEO and the members of the Executive Committee to hold a substantial value in company shares in relation to their annual compensation.

### Safeguards

Our plans contain a number of features to ensure that business risks are appropriately managed, while delivering sustainable returns to shareholders. In particular, safeguards are maintained to limit circumstances in which inappropriate risks might be taken:

Our incentive programs have an appropriate balance between short-term and long-term performance measures with different time horizons and pay out forms (cash and equity).

All incentive plan payouts are capped at 200% of target.

Our executive employment contracts include clawback clauses, and do not contain provisions for severance payments, or change-of-control clauses.

Employment contracts for our CEO and the members of the Executive Committee provide a notice period of 12 months.

The Compensation Committee reviews annually the performance of Novartis key executives against the Novartis Values and Behaviors and the performance of Novartis and its divisions.

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# Summary of Compensation Delivery to the CEO and the members of the Executive Committee

Compensation element Base compensation	Purpose Provides a reasonable, competitive level of fixed compensation in recognition of the position and responsibilities held	Performance measurement	Vesting	Target/Cap	<b>Delivery</b> Cash
Short-term incentive Annual incentive	Rewards performance against short-term (annual) individual and divisional or Group targets, and demonstrable progress against longer-term objectives	Business and Individual performance		Target: Up to 60% of base compensation Cap: 200% of target	Cash
Leverage Share Saving Plan "LSSP" / Employee Share Option Plan "ESOP"	Retains key executives within Novartis, while aligning with the long-term interests of our shareholders		LSSP:5-year time-vesting ESOP: 3-year time-vesting		Shares (LSSP: 1:1 / ESOP: 2:1 matching paid out if executive decides to invest the annual incentive in shares)
Long-term incentive Equity plan "Select"	Ties compensation directly to the long-term performance of our shares to further align with the interests of our shareholders	Business and Individual performance at grant	3-year time-vesting	Target: Up to 200% of base compensation Cap: 200% of target	Restricted shares, tradable options or Restricted Share Units (RSU)
Long-Term Performance Plan "LTPP"	Motivates commitment to longer-term objectives and sustained financial performance for our shareholders	Novartis Economic Value Added (NVA) at vesting	3-year performance-vesting	Target: Up to 175% of base compensation Cap: 200% of target	Shares

# COMPENSATION OF EXECUTIVES AND OTHER ASSOCIATES

### 2012 CEO Performance

# Introduction

The CEO's individual objectives for 2012 were based on a balanced scorecard with a mix of quantitative and qualitative targets for the Group in four key areas; financial performance, innovation and growth, organizational health and customer satisfaction; and adherence to our values and behaviors. Below is a review of his 2012 performance in each area.

# Financial Performance

The CEO's objectives for 2012 included financial targets based on net sales, operating income, earnings per share and free cash flow. Overall performance for the Group in 2012 was in line with

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expectations set at the beginning of the year, with strong performance from the Pharmaceuticals Division, in particular, driving Group net sales in line with targets and the prior year in constant currencies (cc), and core operating income surpassing the target and only slightly below the prior year in cc. This is despite the loss of our exclusivity of *Diovan*, our largest product. Alcon, Animal Health and Sandoz performed in line with financial targets. Due to quality issues and production bottlenecks, goals set for our OTC business and Vaccines and Diagnostics Division were not met.

#### Innovation and Growth

The CEO's objectives for 2012 included targets to extend our lead in innovation and accelerate growth, which are intended to deliver breakthroughs in areas of highest medical unmet need and help mitigate the effect of the loss of our exclusivity of *Diovan*. Overall performance for the Group in 2012 exceeded the goals set by the Board. Novartis invested more than \$9 billion in research and development, significantly advancing our promising pipeline projects and securing 17 major approvals across our portfolio in 2012. The Novartis pharmaceuticals pipeline is expected to deliver a record number of near-term pivotal study readouts, filings and approvals which, together with recently launched products, is expected to drive sales growth. In 2012, our Pharmaceutical R&D projects include 71 new compounds, which is among the highest in the industry and Sandoz had 12 first-to-file and Vaccines and Diagnostics received a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) for *Bexsero*. Sales from recently launched products accounted for 29% of Group net sales, while continually improved growth in emerging markets contributed \$13.8 billion to Group net sales.

### Organizational Health

The CEO's objectives for 2012 included goals for strengthening quality control, driving productivity, developing people and enhancing the Group's reputation. In 2012, Novartis made a significant investment and strengthened measures toward achieving "quality beyond compliance." As a result, the vast majority of inspections by regulatory authorities were assessed as good or satisfactory. While there is still work to do at our Consumer Health facility in Lincoln, Nebraska and at some of the Sandoz sites, our Broomfield, Colorado site, which was under an FDA warning letter, had a satisfactory re-inspection by the FDA and achieved compliance. Productivity measures helped us to achieve overall savings of around \$2.8 billion in 2012 for the Group. We further deepened and broadened programs to strengthen our leadership, to develop talent and to renew our focus on employee engagement.

#### **Customer Satisfaction**

In 2012, our "Customers First" initiative to improve cross-divisional collaboration and better serve our customers' needs delivered incremental sales of more than \$0.8 billion, exceeding the objective.

### Performance Evaluation system and compensation determination

To foster a high performance culture, Novartis applies a uniform People Performance Management process worldwide, based on quantitative and qualitative criteria, including Novartis Values and Behaviors. Novartis associates, including the CEO and the members of the Executive Committee, are subject to a three-tier formal process.

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#### Objective Setting

Objective setting for the CEO

At the beginning of each performance year, the Chairman meets with the CEO to discuss his objectives for the coming year following a balanced scorecard approach. The Board of Directors reviews and approves these objectives and ensures that they are in line with the Group's goals of fostering sustainable performance, balancing short- and long-term goals, and not rewarding inappropriate or excessive risk taking at the expense of the long-term condition of the Group.

The financial criteria for short-term performance appraisal of the CEO include growth objectives for net sales, operating income, net income, free cash flow, earnings per share as well as relevant market shares. For long-term performance appraisal, the financial criterion is the Novartis Economic Value Added (NVA). NVA is a measure of the Group's performance, taking into account Group operating income adjusted for interest, taxes and charge for the cost of capital or, more simply, the value created in excess of the expected return of the company's investors (i.e. the shareholders and debt holders). For more information regarding NVA calculation, see "Item 5. Operating and Financial Review and Prospects Item 5.A. Operating Results Novartis Economic Value Added".

Objective setting for the members of the Executive Committee and associates

At the beginning of each year, the CEO and each of the executives directly reporting to him determine together the business objectives and respective metrics applicable to each of the divisional and global functional leaders. The CEO then presents the business objectives of the members of the Executive Committee to the Board of Directors.

In the same manner, each line manager and each associate directly reporting to her or him set the objective and metrics applicable to the next-level associate. As a principle, all written objectives are reviewed by two hierarchical levels, including the direct and the indirect supervisors.

Objectives are set each year at ambitious levels to motivate a high degree of business performance appropriately balancing the short- and long-term objectives.

Decisions and actions must be consistent with Novartis Values and Behaviors, which describe the desired conduct of associates and set boundaries and guidelines as an important building block for the culture of our Group. The Novartis Values and Behaviors focus on quality, innovation and integrity.

Novartis does not disclose specific business objectives for the upcoming years, as it would give our competitors insight into our key market strategies and areas that could be used against Novartis competitively by industry consultants or competitors targeting existing customers.

# Performance Evaluation

Our performance management system and "pay-for-performance" principle have spurred a culture of meritocracy at Novartis. We believe that pay-for-performance is only sustainable when fair performance evaluation procedures ensure integrity and fairness. Performance evaluation is conducted at all levels of the organization.

The People Performance Management evaluation process consists of two reviews per year a mid-year and a year-end review. During such formal meetings, associates and managers evaluate performance against the objectives set at the beginning of the year. In assessing performance, managers focus on results-oriented measures, as well as on how results were achieved. The "four eyes" principle ensures that associates' annual objectives and performance evaluations are reviewed separately by two levels of supervisors.

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Our People Performance Management evaluation process is complemented with an annual Organization and Talent Review in which organizational needs and career aspirations of associates are discussed. The review includes the assessment of strengths, weaknesses and potential for personal growth. The Organization and Talent Review has become an integral tool for top management in succession planning, and the scope of the program has steadily expanded globally throughout the organization.

Because performance appraisals impact significant elements of reward, we review each year the consistency of performance ratings across the entire Group.

Process for performance evaluation of the CEO

At the end of a business year, the CEO prepares and presents to the Chairman and, later, to the Board of Directors the actual results against the previously agreed-upon objectives, taking into account the audited financial results as well as Novartis Values and Behaviors. On this basis, the Board of Directors discusses the performance of the CEO without him being present. It evaluates the extent to which targeted objectives have been achieved and, to the extent possible, compares these results with peer industry companies, taking into account general economic and financial criteria and industry developments. The Board of Directors later shares its assessment with the CEO. In addition, the Board of Directors assesses periodically the Group business performance and progress of the CEO against his objectives and incentive plan targets.

Process for performance evaluation of the members of the Executive Committee

In January, the Board of Directors meets with the CEO to review and discuss the performance and objectives of the members of the Executive Committee for the previous year, taking into account the financial results, the level of achievement of financial and non-financial objectives, as well as Novartis Values and Behaviors and the general economic and business environment. In addition to the year-end review, the mid-year performance of the CEO is reviewed by the Chairman while the results of the members of the Executive Committee are evaluated by the CEO and then discussed with the Chairman. As for the CEO, the Board of Directors assesses, periodically the Group or divisional business performance and progress of the members of the Executive Committee against their objectives.

#### **Compensation Determination**

Compensation determination for the CEO

Based on the performance evaluation made by the Board of Directors, the Compensation Committee decides at its January meeting on the CEO's total compensation and the target compensation for the coming year without the presence of the CEO. In reaching its decision, the Compensation Committee takes into account other relevant factors, including available benchmark information and the advice of the Compensation Committee advisor.

Compensation determination for the members of the Executive Committee

In the presence of the CEO and based on his recommendations, the Compensation Committee decides on the variable compensation for the members of the Executive Committee and other selected key executives for the previous year. At the same meeting, the Compensation Committee decides on the target compensation for these executives for the coming year.

Compensation determination for other associates

Based on the year-end performance rating, line managers and next-level line managers determine the incentive awards for each associate under review, as well as the target compensation for the coming year. The Compensation Committee determines the grants for all equity compensation plans in aggregate.

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#### **Executive compensation program and structure**

### Philosophy and Compensation principles

Philosophy and goals

Since Novartis was created, management has forged a distinctive culture and inspired all associates with the shared aspiration of being one of the world's most respected healthcare companies. In order to realize this aspiration, Novartis must attract and retain the best-in-class talent worldwide and reward associates according to their performance.

Our compensation system aims to foster personal accountability based on clear individual and organizational objectives, and also underlines the importance of competence and integrity as drivers of sustainable business success. Consequently, compensation includes, in addition to a fixed base compensation, a significant variable compensation element. The size of the variable compensation element is based on Group or divisional results and on individual performance against a written set of objectives. Moreover, to further align our compensation programs with the interests of shareholders, a large proportion of variable compensation for executives is paid in the form of equity Novartis shares (or similar equity instruments) or share options with a three-year vesting period.

The core principles of our compensation policy and people development have resulted in both sustained performance and superior leadership. Novartis has reported a strong performance year over year and, for the 16<sup>th</sup> consecutive year, propose to raise the annual dividend payout to shareholders.

#### Compensation principles

The compensation system for Novartis associates is based on the following five principles:

### Principle I: Pay-for-Performance

Compensation of executives and associates is strongly linked to achievements of business and individual performance objectives. The objectives are set at ambitious levels each year to motivate a high degree of business performance with emphasis on short- and long-term quantifiable objectives.

### Principle II: Competitive Compensation

Compensation at competitive levels are essential to attract and retain talented and diverse associates. Our target compensation levels reflect total compensation for comparable positions at relevant benchmark companies.

#### Principle III: Balanced Rewards to Create Sustainable Value

Shareholders expect their investment to deliver sustainable returns while ensuring that risks are appropriately managed. Novartis incentives underpin the long-term strategic planning that is essential to address the challenges of innovation and the long development and commercialization cycles that characterize our industry. We believe that the way in which we motivate and reward our associates encourages performance, loyalty and entrepreneurship, and creates sustainable value which is in the long-term interest of our shareholders, employees and communities.

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#### Principle IV: Business Ethics

At Novartis, all associates are expected to achieve their business results through ethical practices, reflected also in our Code of Conduct. To ensure that these requirements are complied with, Novartis has implemented a number of safeguards, such as a stringent risk management policy and clawback provisions, for most compensation plans and for the majority of associates.

#### Principle V: Equity Ownership

Investors expect the leaders of the companies to act like owners. In the Board of Directors' view, that alignment works best when key executives have meaningful multiples of their base compensation invested in the equity of their company. Novartis grants equity compensation, which for the most senior executives represents a substantial portion of total compensation. Under this principle, Novartis sets share ownership guidelines for a number of key executives of the Group.

#### Setting compensation level and performance targets for variable pay

For Novartis to attract and retain key talent it is important to offer competitive compensation levels on a global basis. In line with the compensation philosophy of Novartis the CEO, a member of the Executive Committee, or an associate achieving their objectives is generally awarded a compensation level compared to the median level of the relevant benchmarks. In the event of under- or over-performance the actual compensation may be lower or higher than the benchmark median. In the event of exceptional and sustained performance actual compensation may be awarded at the top quartile of the market benchmarks of peer companies in order to encourage and reward superior performance.

The Compensation Committee reviews the compensation of the CEO and of the members of the Executive Committee annually and compares them to the relevant compensation level of similar positions at peer companies. For this purpose, Novartis uses benchmark data from well-known market data providers and other relevant data sources. In particular the mix of short-term and long-term incentives, the mix of cash and share-based compensation, the level of deferred compensation as well as current compensation policies are reviewed. Further, the data analysis conducted by the market data providers takes into account factors such as recent market trends and best practice in compensation. The Compensation Committee's independent advisor reviews and evaluates the data received, and provides additional insight and evaluation as appropriate.

The comparator companies consist of competitors in the healthcare industry which are operating on a global basis and have the same or similar business model, business size, international competition, and need for talent and skills.

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Benchmark criteria (in \$ billion)	Novartis(1)	Benchmark Peers Median <sup>(2)</sup>
Net sales/Revenue	56.7	44.2
Market capitalization	152.0	100.3
Operating income	11.5	10.3
Net income	9.6	6.8
Total assets	124.2	65.1

(1) As of December 31, 2012

(2) As at last reported quarter end

Source: S&P Research Insight, trailing four quarters

Compensation of the CEO and the members of the Executive Committee is benchmarked relative to the healthcare companies in the table above. For other executives, excluding the CEO and the members of the Executive Committee, compensation is benchmarked either relative to these healthcare companies or, for non-industry specific positions, to market data from companies outside of the healthcare industry with scope, size and complexity that approximate the size and nature of the Novartis business. This reflects the fact that competition for talent is not limited to only the healthcare industry.

Elements of our Compensation Programs

The primary elements of our compensation system are:

Annual base compensation: A fixed annual salary

Variable compensation: Rewards for individual and business performance

Benefits: Including pension and healthcare benefits

### Annual Base Compensation (Salary)

The level of base compensation reflects each associate's key areas of responsibilities, job characteristics, seniority, experience and skill sets. It is paid in cash, typically monthly, and is set according to local practice, designed to provide our associates with fixed compensation to ensure a reasonable standard of living relative to that offered by our peer companies.

In general, base compensation is reviewed annually to ensure that competitive pay is maintained.

### Variable Compensation

The goal of variable compensation is to reward Novartis associates according to their performance and in a manner consistent with the "pay-for-performance" principle.

At managerial levels, variable compensation is generally composed of annual cash incentive and an equity based long-term incentive. Novartis believes that variable compensation should specifically emphasize long-term incentives to align the interests of our associates with those of long-term shareholders. This also reflects the crucial importance of innovation and the long product development

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and commercialization cycles that characterize our industry. The amount of variable compensation is based on results and calculated as a percentage (0-200%) of target variable compensation.

#### Short-term incentive

The annual incentive ensures that associates focus on individual objectives and objectives defined by the business over a single financial year. These include objectives such as market share, innovation, and people management, which also positively influence the long-term performance. It rewards performance in the last 12 months in relation to these objectives and reinforces the "pay-for-performance" principle.

In principle, the annual incentive is paid in cash and is capped at 200% of target. However, a number of associates in certain countries and certain key executives worldwide are encouraged to invest their annual incentive in a share savings plan. Under the share savings plan, they will receive their annual incentive awards fully or partially in Novartis shares in lieu of cash. As a reward for their participation in the share savings plan, Novartis matches their investments in shares after a holding period of three or five years. As a rule, no shares are matched under these plans if an associate leaves Novartis prior to the expiration of the holding period for reasons other than retirement, disability or death. Thus, through the participation in the share savings plan our associates are incentivized to remain with Novartis for the long-term, while sharing in the future financial success of Novartis and further aligning with the long-term interests of our shareholders.

Novartis currently has three share savings plans:

Leveraged Share Savings Plan (LSSP): Worldwide 29 key executives were invited to participate in a leveraged share savings plan based on their performance in 2012. Instead of cash, their annual incentive was awarded in shares and subject to a holding period of five years. At the end of the holding period, Novartis will match the invested shares at a ratio of 1-to-1 (i.e. one share awarded for each invested share).

Employee Share Ownership Plan (ESOP): In Switzerland, the ESOP is available to about 13,341 associates. Participants within this plan may choose to receive the incentive (i) 100% in shares, (ii) 50% in shares and 50% in cash or (iii) 100% in cash. After expiration of a three-year holding period of Novartis shares invested under the ESOP, each participant will receive one free matching share for every two Novartis shares invested. A total of 5,557 associates chose to receive shares under the ESOP for their performance in 2012.

*United Kingdom Plan (ESOP UK):* In the United Kingdom, 2,743 associates can invest up to 5% of their monthly salary in shares (up to a maximum of GBP 125) and also may be invited to invest all or part of their net annual incentive in shares. Two invested shares are matched with one share with a holding period of three years. During 2012, 1,576 associates elected to participate in this plan.

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Associates may participate in only one of these plans in any given year.

#### Long-term incentive

The long-term incentive is designed to focus on our objective of long-term sustainable shareholder value creation and to support our "pay-for-performance" principle by using equity based compensation with a three year vesting period.

These long-term incentives awarded by Novartis aim at retaining our key talent, encouraging the realization of multi-year business objectives and aligning our associates with our shareholders' interests by tying the value realized to the change in the share price at vesting.

The equity based long-term incentive is subject to the achievement of predetermined performance objectives either at grant or at vesting.

Novartis offers two long-term incentive plans, the Equity Plan "Select" based on yearly results with a three-year vesting period and the Long-Term Performance Plan based on rolling three-year global performance objectives.

In exceptional cases, Novartis may also grant special share awards.

Novartis uses shares repurchased in the market to fulfill obligations to deliver shares as required by the variable compensation plans and special share awards, thus avoiding any dilution to shareholders.

Novartis does not have any approved conditional capital to obtain shares for delivery of our share awards.

#### Equity Plan "Select"

The Equity Plan "Select" is a global equity incentive plan under which eligible associates, including members of the Executive Committee, may annually be awarded a grant capped at 200% of target. The Equity Plan "Select" allows its participants to choose the form of their equity compensation in restricted shares (or, in some jurisdictions, RSUs<sup>(1)</sup>), tradable share options, or a combination of both, with a vesting period of three years.

Tradable share options expire on their 10th anniversary from grant date. Each tradable share option granted to associates entitles the holder to purchase after vesting (and before the 10th anniversary from grant date) one Novartis share at a stated exercise price that equals the closing market price of the underlying share at the grant date.

The terms of the tradable share options granted since 2009 are shown in the table below.

### **Terms of Share Options**

(1)

		Vesting (years)	
Grant year	Exercise price (CHF/\$)	(CH/other countries)	Term (years)
2013	61.70/66.07	3/3	10
2012	54.20/58.33	3/3	10
2011	54.70/57.07	2/3	10
2010	55.85/53.70	2/3	10
2009	53.65/46.42	2/3	10

In some jurisdictions, Restricted Share Units (RSU) are granted rather than shares. Each RSU is equivalent in value to one Novartis share and is converted into one share at the vesting date. RSUs do not carry any dividend or voting rights, except for the USA where employees receive a dividend equivalent during the vesting period for 2010 and 2011 grants. Each restricted share is entitled to voting rights and payment of dividends during the vesting period.

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If a participant leaves Novartis for reasons other than retirement, disability or death, unvested shares, RSUs and share options are forfeited, unless determined otherwise by the Compensation Committee (for example, in connection with a reorganization or divestment).

A total of 12,352 participants received 0.8 million restricted shares, 6.0 million RSUs and 25.2 million tradable share options under the Novartis Equity Plan "Select" for their performance in 2012, representing a participation rate of about 10% of all full-time-equivalent associates worldwide.

As of December 31, 2012, 95.3 million share options granted to associates were outstanding, covered by an equal number of shares and corresponding to 3.9% of the total number of outstanding Novartis shares.

Approximately 4% of the total equity value awarded under the Equity Plan "Select" was granted to the members of the Executive Committee.

### Long-Term Performance Plan

The Long-Term Performance Plan (LTPP) is an equity plan for key executives designed to foster long-term commitment by aligning the incentives of key executives to the performance of Novartis. The LTPP is offered to selected executives, who are in key positions and have a significant impact on the long-term success of Novartis. It is capped at 200% of target. For members of the Executive Committee, LTPP represents between 20% and 44% of their total variable compensation at target. The rewards are based on rolling three year global performance objectives focused on the Novartis Economic Value Added (NVA) measured annually. The NVA is calculated based on Group operating income adjusted for interest, taxes and cost of capital charge. The performance realization of a plan cycle is obtained right after the end of the third plan year by adding together the annual NVA realizations of all plan years of the plan cycle. The performance ratio for a plan cycle is obtained by dividing the performance realization for the plan cycle with the performance target for the plan cycle, expressing the result as a percentage. The LTPP only allows a payout if the actual NVA exceeds predetermined target thresholds.

To support the alignment of interests of the members of the Executive Committee with those of the Group and of our shareholders, the Long-Term Performance Plan represents a substantial and increasing portion of their variable compensation targets.

On January 17, 2013, 132 key executives earned 456,712 shares under the Long-Term Performance Plan, based on NVA achievement that exceeded our target performance for the performance period 2010 to 2012.

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### **Long-term Performance Plan Participants History**

Grant year = Target setting	Performance period	Award year = Payout in shares	Plan participants (number of key executives)
2013	2013-2015	2016	133
2012	2012-2014	2015	136
2011	2011-2013	2014	136
2010	2010-2012	2013	132
2009	2009-2011	2012	138

Special Share Awards

Selected associates may exceptionally receive special awards of restricted shares or RSUs. These Special Share Awards provide an opportunity to reward outstanding achievements or exceptional performance and aim at retaining key contributors. They are based on a formal internal selection process, in which the individual performance of each candidate is thoroughly assessed at several management levels. The CEO and the members of the Executive Committee are excluded from receiving this type of award.

In exceptional circumstances, special equity grants may be awarded to attract special expertise and new talent into the organization. These grants are consistent with market practice and the Novartis philosophy to attract, retain and motivate best-in-class talent around the world.

Restricted special awards generally have a five-year vesting period. If an associate leaves Novartis for reasons other than retirement, disability or death, unvested shares or RSUs are generally forfeited. Worldwide 787 associates at different levels in the organization were awarded a total of 0.8 million shares or RSUs in 2012.

# Benefits

The primary purpose of pension and healthcare plans is to establish a level of security for associates and their dependents with respect to age, health, disability and death. The level of pension and healthcare benefits provided to associates is country-specific and influenced by local market practice and regulations, and is reviewed regularly.

The Group has a policy to change from defined-benefit (DB) pension plans to defined-contribution (DC) pension plans. All the major plans have now been aligned with our benefits strategy as far as reasonably practicable, with the exception of the Alcon DB pension plans, for which Novartis has established a global timeline for their conversion into DC pension plans.

Novartis may provide other benefits in a specific country according to local market practice and regulations, including length-of service awards and perquisites. Associates who have been transferred on an international assignment can also receive benefits in line with Novartis policies.

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# **Summary of Compensation System**

	Compensation	Performance period at	Method of		Performance n	Performance metrics	
Compensation element	plan	risk	payments	Main drivers	At award	At vesting	participants
Base compensation	Base salary		Cash	Position, experience, sustained performance			All associates
Variable compensation							
Short-term incentive	Annual incentive (including LSSP, ESOP, ESOP UK) <sup>(1)</sup>	12 months	Cash and/or shares	Financial measures such as net sales, operating income, free cash flow, market share, innovation and ongoing efforts tooptimize organizational effectiveness and productivity	Achievement of individual, business and financial annual objectives or achievement of milestones in individual objectives or long-term strategic plans, Novartis Values and Behaviors		16,113 <sup>(2)</sup>
Long-term incentive	Equity Plan "Select"	3 years	Restricted shares, tradable options or RSUs	Financial measures such as net sales, operating income, free cash flow, market share, innovation and ongoing efforts to optimize organizational effectiveness and productivity	Achievement of individual, business and financial annual objectives or achievement of milestones in individual objectives or long-term strategic plans, Novartis Values and Behaviors	Share price	12,352
	Long-Term Performance Plan	3 years	Shares	Achievement of long-term profit, measured through Novartis Economic Value Added (NVA) targets at Group level		Novartis Economic Value Added	132
	Special Share Awards <sup>(3)</sup>	5 years	Restricted shares or RSUs	Rewarding particular achievements or exceptional performance	Selective assessment	Share price	787
Benefits					Position, tenure, age, sustained performance		

If the associate invests the annual incentive into a shares savings plan, any matching shares are subject to risk for the vesting/holding period of five years (LSSP, with a 1:1 matching) or three years (ESOP or ESOP UK, with a 2:1 matching).

Number of participants in LSSP, ESOP, ESOP UK.

(3) Executive Committee members are excluded from receiving this type of award.

#### Target Incentive Levels and Performance Measures

Annual Incentive and Equity Plan "Select"

Under both the annual incentive and Equity Plan "Select," Novartis defines a target incentive as a percentage of base compensation for each participating associate at the beginning of each performance period traditionally the start of each calendar year. Depending on the role and the level of responsibility of the associates, target incentive percentages may reach up to 60% of base compensation for the annual incentive and 200% for the Equity Plan "Select."

The annual incentive and the Equity Plan "Select" are designed to drive the achievement of Novartis' stretched annual financial and operational business targets, as well as the delivery of personal objectives. No awards are granted for performance ratings below a certain threshold.

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The Award Calculation Formula under both the annual incentive and the Equity Plan "Select" is the following:

Business and the individual performance multipliers may range from zero to 1.5, and thus have an equivalent weighting in the formula. However, payouts are subject to a cap at 200% of target.

Performance measures that comprise the business performance factor drive the achievement of stretched annual financial and operational targets at Group, divisional and regional levels. These targets are determined based on each executive's area of responsibility, at either Group, divisional or regional level, and may include targets based on net sales, operating income, free cash flow, market share, personnel cost or milestones in research and development. These financial and operational targets have been selected because they define in a balanced way how successful we are in meeting our strategic objectives and creating sustainable value to our shareholders.

The individual performance factor comprises two separate elements. The first element drives the achievement of individually set financial and non-financial objectives. Depending on functional responsibility, non-financial objectives typically include innovation; product launches; successful implementation of growth and productivity initiatives; process improvements; leadership and people management and successful acquisitions, disposals and licensing transactions. The second element ensures that performance is achieved in line with the highest standards in business conduct, as outlined in the Novartis Values and Behaviors. Our leaders are expected to exhibit role-model behavior on a daily basis, and to inspire other associates to do the same.

Once performance has been evaluated, a matrix determines the individual performance factor which is derived from the combination of the two ratings received.

Typically, the annual incentive is paid out in February following the realization of the yearly objectives. Performance under the Equity Plan "Select" is further determined by the development of the share price over the following three-year vesting period, and is contingent on continued employment with Novartis.

For those who have chosen to receive their annual incentive under the LSSP or ESOPs plans, as well as for those receiving awards under the Equity Plan "Select" the number of shares awarded is determined by dividing the actual incentive amount by the closing price of the shares on the grant date. In North America, if associates choose to receive part or all of their grant under the Equity Plan "Select" in tradable share options on American Depositary Shares (ADSs), the resulting number of tradable share options is determined by dividing the respective incentive amount by a value that equals 95% of the value of the options on ADSs as determined in accordance with International Financial Reporting Standards (IFRS). For associates in other countries, the divisor equals 90% of the IFRS value of options on shares.

Long-Term Performance Plan

LTPP drives the achievement of long-term shareholder value creation over rolling three year performance periods. The performance measure (NVA) is assessed annually and targets are set at the

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beginning of each year. Following the three-year performance period, achievement against the three annual targets is aggregated in order to determine the final payout.

Depending on the role and the level of responsibility of the associates, the target incentive percentages may reach up to 175% of base compensation for LTPP. If performance over the three year vesting period falls below a predetermined threshold of 90% of target, or if the participant leaves Novartis during the performance period for reasons other than retirement, disability or death, none of the award vests. A maximum of 200% of the target award may vest for outstanding performance.

At the beginning of every performance period, plan participants are granted RSUs, which are converted into Novartis shares after the performance period.

At the end of the three-year performance period, the Compensation Committee adjusts the number of RSUs earned based on actual performance. RSUs are converted into unrestricted Novartis shares without an additional vesting period. In the United States, awards may also be delivered in cash under the US deferred compensation plan.

### Proposed Changes to the Compensation System for the CEO and the members of the Executive Committee from 2014

Our Board and management continually reach out to our stakeholders to gather feedback on our compensation system to see if there are ways we can better align with the interests of our shareholders and promote transparency.

Based on this, the Compensation Committee has undertaken a strategic review of the compensation system over the last 12 months and the Board of Directors has approved a number of changes to apply from 2014 onwards, subject to a consultative shareholder vote at the Annual General Meeting in 2013.

The overall design of the proposed program includes an annual incentive plan and two separate long-term incentive plans.

Further details of the proposed changes are set out in a separate summary attached to the Notice of Annual General Meeting 2013.

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### Proposed Changes to the Compensation System for the CEO and the members of the Executive Committee from 2014 KEY HIGHLIGHTS

As from January 2014, the following changes to the compensation programs for the CEO and the members of the Executive Committee would apply:

All variable compensation is performance-based and separate performance measures are used for short-term and long-term incentive plans.

The short-term incentive plan is based on an individual balanced scorecard of 1-year financial and non-financial performance measures, together with assessed values and behaviors. This incentive is paid half in cash and half in shares deferred for 3 years.

The two long-term incentive plans are based on different performance measures and are paid in shares after a 3-year performance period.

The Long-Term Performance Plan (LTPP) includes 3-year forward-looking financial and innovation measures, either at Group or divisional level, depending on the role and responsibilities held by the executive.

The Long-Term Relative Performance Plan (LTRPP) rewards for performance of the Group's Total Shareholder Return (TSR) measured over a 3-year period relative to a peer group of comparator companies as determined by the Board.

The new compensation programs for executives no longer contain discretionary or matching share awards or share options.

### Summary of Proposed Program

#### Compensation of members of the Executive Committee for 2012

The following compensation table discloses the compensation earned by the CEO and the members of the Executive Committee for performance in 2012. The following paragraphs describe the principles underlying the data in the table.

### Alignment of Reporting and Performance

The compensation table synchronizes the reporting of annual compensation with the performance in the given year, i.e., all amounts awarded for performance in 2012, including the future LSSP/ESOP match, are disclosed in full.

#### Disclosure Structure

The compensation table shows the compensation granted to the CEO and each member of the Executive Committee for performance in 2012 for all compensation elements base compensation, variable compensation and benefits as previously described.

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The column "Future LSSP/ESOP match" reflects shares to be awarded in the future if the Executive Committee member remains with Novartis for at least three or five years, respectively.

### Valuation Principles

(3)

(4)

In order to allow a comparison with other companies, the Compensation Committee decided to disclose shares, restricted shares, RSUs and ADS at their market value on the date of grant. Market value is the current quoted share price at which a director or an associate is granted a share, a restricted share or a restricted share unit at grant date. The market value of share options is calculated by using an option pricing valuation model as per grant date.

# **Executive Committee Member Market Value Compensation for Performance Year 2012**<sup>(1)</sup>

	(	Base compensation			compensatio	n		Bene	efits	Total	•	Total compensation
			Short- incentiv		Long-term i	Long-term incentive plans						Including
	Currency	Cash (Amount)	Cash (Amount)	Shares (Market value) <sup>(2)</sup>	Equity Plan "Select" Shares Op (Market(M value) <sup>(3)</sup> val	n I otion ark	et(Market	Pension benefits (Amount) <sup>(6)</sup> (	Other benefits  (Amount)(7)		Future LSSP/ESOI match <sup>(9)</sup> Shares (Market value)	future PLSSP/ESOP match(10,11)  (Amount)
Joseph Jimenez (Chief Executive												
Officer)	CHF	2,025,000	1,370,300	0	4,795,941	0	4,747,013	161,200	128,734	13,228,188	0	13,228,188
Juergen		,,	,,.		, , .		,,	, , , , ,	-,	., ., .,		, , , , , ,
Brokatzky-Geiger	CHF	708,750	0	625,330	1,250,536	0	731,145	148,594	10,084	3,474,439	625,330	4,099,769
Kevin Buehler <sup>(12)</sup>	USD	1,118,333	202,897	504,048	2,827,532	0	1,753,300	413,056	62,930	6,882,096	504,048	7,386,144
Felix R. Ehrat	CHF	743,333	0	750,149	1,500,112	0	432,702	158,498	0	3,584,794	750,149	4,334,943
David Epstein	USD	1,158,332	525,953	727,166	3,132,643	0	1,666,814	325,563	26,191	7,562,662	727,166	8,289,828
Mark C. Fishman	USD	990,000	23,265	966,736	3,960,038	0	1,547,029	242,832	118,319	7,848,219	966,736	8,814,955
Jeff George	CHF	791,667	220,000	220,022	880,027	0	636,250	111,932	55,412	2,915,310	110,011	3,025,321
George Gunn	CHF	862,500	716,300	0	1,193,710	0	1,213,762	108,382	0	4,094,654	0	4,094,654
Naomi Kelman (until February 29,												
$2012)^{(13)}$	USD	102,782	51,667	0	0		0	3,196	904,469	1,062,114	0	
Andrin Oswald	CHF	791,667	0	304,058	608,054		636,250	118,132	38,520	2,496,681	304,058	2,800,739
Jonathan Symonds	CHF	916,667	0	621,011	1,552,557	0	1,377,021	161,817	17,135	4,646,208	621,011	5,267,219
Brian McNamara (as from March 1,												
2012)(14)	USD	500,000	94,169	140,002	464,869	0	260,580	45,053	19,710	1,524,383	140,002	1,664,385
Total <sup>(15)</sup>	CHF	10,466,057	3,148,166	4,711,715	21,513,910	0	14,673,602	1,933,597	1,310,446	57,757,493	4,601,704	62,359,197

Does not include reimbursement for travel and other necessary business expenses incurred in the performance of their services as these are not considered compensation.

Participants elected to invest some or all of the value of their annual incentive in the Leveraged Share Savings Plan (LSSP) with a five-year vesting period or the Swiss Employee Share Ownership Plan (ESOP) with a three-year vesting period rather than to receive cash.

Novartis shares granted under the Novartis Equity Plan "Select" have a three-year vesting period.

Novartis share options granted under the Novartis Equity Plan "Select" are tradable. Share options granted outside North America will expire on January 17, 2023, have a three-year vesting period and have an exercise price of CHF 61.70 per share (the closing price of Novartis shares on the grant date of January 17, 2013). Based on the option pricing valuation model as per grant date, the value of the share options granted outside North America used in this table was CHF 4.28. Share options on ADSs granted to participants in North America will expire on January 17, 2023, have a three-year vesting period and an exercise price of \$66.07 per ADS (the closing price of Novartis ADSs on the grant date of January 17, 2013). Based on the option

pricing valuation model as per grant date, the value of the share options on ADSs granted to participants in North America used in this table was \$4.37.

- (5) Awarded based on the achievement of Novartis Economic Value Added (NVA) objectives over the performance period ended December 31, 2012.
- (6) Service costs of pension and post-retirement healthcare benefits accumulated in 2012.
- Includes perquisites and other compensation valued at market price. Does not include cost allowances and tax-equalization payments regarding the international assignment of David Epstein, Jeff George and Andrin Oswald. Does not include an annual pension in payment for Kevin Buehler as a result of a change of control clause (\$491,174). Does

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(12)

(14)

org om ntil 12) not include dividend equivalents paid in 2012 to Kevin Buehler (\$529,387) for pre Alcon merger RSUs grants, to David Epstein (\$138,011), Mark C. Fishman (\$189,845) and Brian McNamara (\$17,122) for RSUs grants made in or prior to 2010.

- The value of all equity grants included in this table has been calculated based on market value.
- (9) Reflects shares to be awarded in the future under the share saving plans, either the five-year Leveraged Share Savings Plan (LSSP) or the three-year Swiss Employee Share Ownership Plan (ESOP). Participants will receive additional shares ("matching shares") after the expiration of either the five- or three-year vesting period.
- (10)The values of the shares, RSUs and share options reflected in this table have been calculated based on market value. The closing share price on the grant date January 17, 2013 was CHF 61.70 per Novartis share and \$66.07 per ADS.
- (11) All amounts are gross amounts (i.e., before deduction of social security and income tax due by the executives). The employer social security contribution is not included.
- Excludes 35,153 performance shares awarded to Kevin Buehler, against the share price of \$54.51 for performance prior to the Alcon merger.
- (13)Naomi Kelman stepped down from the Executive Committee as per February 29, 2012. The base compensation and benefits information in the table reflects her pro rata compensation over the period from January 1, 2012 to February 29, 2012 (i.e. the period during which she was member of the Executive Committee). The other compensation ("Other benefits") includes the contractual compensation and benefits from March 1, 2012 to December 31, 2012 due in compensation for the twelve-month notice set forth in her employment contract. The other compensation ("Other benefits") does not include the fair market compensation (\$1,263,223 related to the period between March 1, 2012 and December 31, 2012) for refraining to compete with any business of Novartis for twelve months following her departure. Ms. Kelman will receive this payment in 2013 partly in cash and partly in shares subject to her continued compliance with the non-compete terms. Of the 88,000 shares reported in the Annual Report 2011 as a Special Share Award, 70,500 shares have forfeited, while 17,500 shares contractually vested in 2012.
- The table reflects the compensation as Permanent Attendee to the Executive Committee from March 1, 2012 until December 31, 2012.
- (15)Amounts in USD for Kevin Buehler, David Epstein, Mark C. Fishman, Naomi Kelman and Brian McNamara were converted at a rate of CHF 1.00 = \$1.067, which is the same average exchange rate used in the Group's consolidated financial statements.

# Executive Committee Member Market Value Realized/Unrealized Compensation for Performance Year 2012<sup>(1)</sup>

	Realized compensation							Unrealized compensation						Total
		Base compensation	Short- term incentive plans Cash	Long-Term Performance Plan	Other benefits			Equity Plan "Select"	Future LSSP/ESOP match					
		Cash	(Amount) and Shares (Market	Shares (Market				Shares and Options (Market	Shares (Market					
	Currency	(Amount)	value)	value)	(Amount)	(Amount)	%(2)	value)	value)	(Amount)	%(2)	(Amount)	%(2)	(Amount)
seph Jimenez nief Executive														
ficer)	CHF	2,025,000	1,370,300	4,747,013	128,734	8,271,047	63%	4,795,941	. 0	4,795,941	36%	161,200	1%	13,228,18
ergen														
okatzky-Geiger	CHF	708,750	625,330	731,145	10,084	2,075,309	51%	1,250,536	625,330	1,875,866	46%	148,594	3%	4,099,76
vin Buehler	USD	1,118,333	706,945	1,753,300	62,930	3,641,508	49%	2,827,532	504,048	3,331,580	45%	413,056	6%	7,386,14
lix R. Ehrat	CHF	743,333	750,149	432,702	0	1,926,184	44%	1,500,112	750,149	2,250,261	52%	158,498	4%	4,334,94
vid Epstein	USD	1,158,332	1,253,119	1,666,814	26,191	4,104,456	50%	3,132,643	727,166	3,859,809	47%	325,563	3%	8,289,82
ark C. Fishman	USD	990,000	990,001	1,547,029	118,319	3,645,349	41%	3,960,038	966,736	4,926,774	56%	242,832	3%	8,814,95
f George	CHF	791,667	440,022	636,250	55,412	1,923,351	64%	880,027	110,011	990,038	33%	111,932	3%	3,025,32
orge Gunn	CHF	862,500	716,300	1,213,762	0	2,792,562	68%	1,193,710	0	1,193,710	29%	108,382	3%	4,094,65
omi Kelman ntil February 29,	USD	102 782	51 667	0	904 469	1.058.918	100%	C	0	0	0%	3 196	0%	1.062.11

CHF	791,667	304,058	636,250	38,520	1,770,495	63%	608,054	304,058	912,112	33%	118,132	4%	2,800,73
CHF	916,667	621,011	1,377,021	17,135	2,931,834	56%	1,552,557	621,011	2,173,568	41%	161,817	3%	5,267,21
USD	500,000	234,171	260,580	19,710	1,014,461	61%	464,869	140,002	604,871	36%	45,053	3%	1,664,38
CHF	10,466,057	7.859.881	14.673.602	1.310.446	34,309,987	55%	21.513.910	4,601,704	26,115,614	42%	1.933.597	3%	62,359,19
	CHF	CHF 916,667 USD 500,000	CHF 916,667 621,011 USD 500,000 234,171	CHF 916,667 621,011 1,377,021 USD 500,000 234,171 260,580	CHF 916,667 621,011 1,377,021 17,135  USD 500,000 234,171 260,580 19,710	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834</b> USD 500,000 234,171 260,580 19,710 <b>1,014,461</b>	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56%</b> USD 500,000 234,171 260,580 19,710 <b>1,014,461 61%</b>	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56%</b> 1,552,557 USD 500,000 234,171 260,580 19,710 <b>1,014,461 61%</b> 464,869	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56%</b> 1,552,557 621,011 USD 500,000 234,171 260,580 19,710 <b>1,014,461 61%</b> 464,869 140,002	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56%</b> 1,552,557 621,011 <b>2,173,568</b> USD 500,000 234,171 260,580 19,710 <b>1,014,461 61%</b> 464,869 140,002 <b>604,871</b>	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56</b> % 1,552,557 621,011 <b>2,173,568 41</b> % USD 500,000 234,171 260,580 19,710 <b>1,014,461 61</b> % 464,869 140,002 <b>604,871 36</b> %	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56</b> % 1,552,557 621,011 <b>2,173,568 41</b> % <b>161,817</b> USD 500,000 234,171 260,580 19,710 <b>1,014,461 61</b> % 464,869 140,002 <b>604,871 36</b> % <b>45,053</b>	CHF 916,667 621,011 1,377,021 17,135 <b>2,931,834 56%</b> 1,552,557 621,011 <b>2,173,568 41% 161,817 3%</b> USD 500,000 234,171 260,580 19,710 <b>1,014,461 61%</b> 464,869 140,002 <b>604,871 36% 45,053 3%</b>

<sup>(1)</sup>See also detailed information provided in the table "EXECUTIVE COMMITTEE MEMBER COMPENSATION FOR PERFORMANCE YEAR 2012 (Market value)" on the previous page.

<sup>(2)</sup> Percentage of total compensation.

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Realized compensation is the portion that is earned and paid immediately.

Unrealized compensation is the portion that is deferred and prospectively payable at a future date, subject to performance and employment conditions at the end of the performance cycle.

# **Executive Committee Member Equity Awards for Performance Year 2012 (Number of equity instruments)**

		Variable cor	npensation		
	Short-term incentive plans		Long-term incentive plans		
	Shares (Number) <sup>(2)</sup>	Equity Plan Shares (Number) <sup>(3)</sup>	n "Select" Options (Number) <sup>(3)</sup>	Long-Term Performance Plan Shares (Number)	Future LSSP/ESOP match Shares (Number)
Joseph Jimenez (Chief Executive					
Officer)	0	77,730	0	76,937	0
Juergen Brokatzky-Geiger	10,135	20,268	0	11,850	10,135
Kevin Buehler	7,629	42,796	0	26,537	7,629
Felix R. Ehrat	12,158	24,313	0	7,013	12,158
David Epstein	11,006	47,414	0	25,228	11,006
Mark C. Fishman	14,632	59,937	0	23,415	14,632
Jeff George	3,566	14,263	0	10,312	1,783
George Gunn	0	19,347	0	19,672	0
Naomi Kelman (until February 29, 2012)	0	0	0	0	0
Andrin Oswald	4,928	9,855	0	10,312	4,928
Jonathan Symonds	10,065	25,163	0	22,318	10,065
Brian McNamara (as from March 1,					
2012)(1)	2,119	7,036	0	3,944	2,119
Total	76,238	348,122	0	237,538	74,455

<sup>(1)</sup> The table reflects the compensation as Permanent Attendee to the Executive Committee from March 1, 2012 until December 31, 2012.

<sup>(2)</sup> These shares have a five-year vesting period under LSSP and a three-year vesting period under ESOP.

These shares and the options awarded under the Equity Plan "Select" have a three-year vesting period.

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As the table below shows, most executive compensation is variable and awarded under the long-term incentive plans. This ensures alignment with the interests of Novartis and its shareholders.

# Executive Committee Member Actual Compensation Mix in 2012 Base and Variable Compensation (1)

	Variable (%)				
	Base salary	Annual incentive	Long-term incentive <sup>(2)</sup>		
Joseph Jimenez	15.7%	10.6%	73.8%		
Juergen Brokatzky-Geiger	21.4%	18.9%	59.8%		
Kevin Buehler	17.5%	11.0%	71.5%		
Felix R. Ehrat	21.7%	21.9%	56.4%		
David Epstein	16.1%	17.4%	66.6%		
Mark C. Fishman	13.2%	13.2%	73.6%		
Jeff George	28.8%	16.0%	55.2%		
George Gunn	21.6%	18.0%	60.4%		
Andrin Oswald	33.8%	13.0%	53.2%		
Jonathan Symonds	20.5%	13.9%	65.6%		
Brian McNamara (as from March 1, 2012) <sup>(3)</sup>	34.3%	16.0%	49.7%		
Total <sup>(4)</sup>	19.2%	14.4%	66.4%		

### Shares and Share Options owned by members of the Executive Committee

The following tables show the total number of vested and unvested Novartis shares (including share units but excluding unvested matching share units from leveraged share savings plans and unvested target units from the Long-Term Performance Plan) and the total number of share options owned by members of the Executive Committee as of January 17, 2013.

As of January 17, 2013, none of the members of the Executive Committee together with "persons closely linked" to them (see definition under "Share Ownership Requirements") owned 1% or more of the outstanding shares of Novartis, either directly or through share options.

<sup>(1)</sup> Excludes pension, other benefits and future LSSP/ESOP match.

<sup>(2)</sup> Long-term incentive includes Equity Plan "Select" and LTPP grants.

<sup>(3)</sup> Permanent Attendee to the Executive Committee.

Excludes Naomi Kelman who stepped down from the Executive Committee as per February 29, 2012.

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As of December 31, 2012, all members of the Executive Committee who have served at least three years on the Executive Committee have met or exceeded their personal Novartis ownership requirements.

# **Shares Owned by Executive Committee Members**

Number of shares <sup>(1)</sup>
565,007
268,498
502,859
52,616
319,532
439,946
137,666
267,468
150,810
202,375
41,160

Total<sup>(3)</sup> 2,947,937

(1)

# **Share Options Owned by Executive Committee Members**

				Number of sl	hare options <sup>(1</sup>	1)	
	2013	2012	2011	2010	2009	Other	Total
Joseph Jimenez					552,076	157,266	709,342
Juergen Brokatzky-Geiger					75,705	255,452	331,157
Kevin Buehler						605,877(2)	605,877
Felix R. Ehrat							
David Epstein							
Mark C. Fishman						604,129	604,129
Jeff George			141,396	97,827	15,359	1,793	256,375
George Gunn						94,371	94,371
Andrin Oswald						5,633	5,633
Jonathan Symonds				54,348			54,348
Brian McNamara (as from							
March 1, 2012) <sup>(3)</sup>						88,005	88,005
Total <sup>(4)</sup>	0	0	141,396	152,175	643,140	1,812,526	2,749,237

Includes holdings of "persons closely linked" to members of the Executive Committee (see definition under Share and Share Options by Members of the Board of Directors).

<sup>(2)</sup> Permanent attendee to the Executive Committee.

Excludes 97,906 shares owned as per February 29, 2012 by Naomi Kelman who stepped down from the Executive Committee at this date.

Share options disclosed for a specific year were granted in that year under the Novartis Equity Plan "Select." The column "Other" refers to share options granted in 2008 or earlier, to share options granted to these executives while they were not Executive Committee members (nor Permanent

Attendees), and to share options bought on the market

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by the Executive Committee members or "persons closely linked" to them (see definition under Share and Share Options Owned by Members of the Board of Directors).

- (2) Consists of share settled appreciation rights resulting from conversion of Alcon equity into Novartis equity.
- (3) Permanent Attendee to the Executive Committee.
- Excludes Naomi Kelman who stepped down from the Executive Committee as per February 29, 2012 and who was not awarded options.

### Loans to members of the Executive Committee

No loans were granted to current or former members of the Executive Committee during 2012. No such loans were outstanding as of December 31, 2012.

# Other payments to members of the Executive Committee

During 2012, no payments (or waivers of claims) other than those set out in the Executive Committee Member Compensation table (including its footnotes) were made to current members of the Executive Committee or to "persons closely linked" to them (see definition under "Compensation of the Board of Directors").

## Payments to former members of the Executive Committee

During 2012, no payments (or waivers of claims) were made to former members of the Executive Committee or to "persons closely linked" to them (see definition under "Compensation of the Board of Directors"), except for an amount of CHF 1,156,414, which includes CHF 1,125,000 paid to a former member of the Executive Committee in relation to his obligation to refrain from activities that compete with any business of Novartis and an amount of CHF 31,414 as other benefits related to his Executive Committee tenure.

# **COMPENSATION GOVERNANCE**

### **Legal Framework**

The Swiss Code of Obligations as well as the Corporate Governance Guidelines of the SIX Swiss Exchange require listed companies to disclose certain information about the compensation of members of the Board of Directors and members of the Executive Committee, their equity participation in the Group as well as loans made to them. This Annual Report fulfills that requirement. In addition, our Annual Report is in line with the principles of the Swiss Code of Best Practice for Corporate Governance of the Swiss Business Federation (economiesuisse).

# **Decision-making authorities**

Authority for decisions related to compensation are governed by the Articles of Incorporation, the Board Regulations and the Compensation Committee Charter, which are published on the Novartis website: www.novartis.com/corporate-governance. The main responsibilities of the Compensation Committee are shown under "Corporate Governance Report Our Board of Directors Role of the Board of Directors and the Board Committees."

The Compensation Committee serves as the supervisory and governing body for compensation policies and plans within Novartis and has overall responsibility for determining, reviewing and proposing compensation policies and plans for approval by the Board of Directors in line with the Compensation Committee Charter. The main discussion points and conclusions of each meeting of the Compensation Committee are summarized in a brief report to the next meeting of the full Board.

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The Compensation Committee carefully analyzes and discusses on an ongoing basis (but at least annually) the trends and developments in the field of compensation and corporate governance as well as all compensation plans and levels with guidance from outside experts and consultants. The goal is to strengthen the interrelation between the compensation plans and the Group's performance. It also reviews the compensation system to ensure that it does not encourage inappropriate or excessive risk taking and instead encourages behaviors that support sustainable value creation.

The Compensation Committee is composed exclusively of members of the Board of Directors who meet the independence criteria set forth in our Board Regulations. In 2012, Enrico Vanni has been designated chairman of the Compensation Committee. Currently, the Compensation Committee has the following five members: Enrico Vanni (chair), William Brody, Srikant Datar, Ulrich Lehner and Marjorie M.T. Yang.

The Compensation Committee held six meetings in 2012.

### **Compensation Authorization Levels**

Decision on Compensation of Board members	Recommendation Compensation Committee	Authority Board of Directors
Compensation of the Chief Executive Officer	Chairman of the Board	Compensation Committee
Compensation of the Executive Committee members and other selected key executives	Chief Executive Officer	Compensation Committee
Special Share Awards	Chairman of the Board or Chief Executive Officer	Compensation Committee

The General Meeting holds a consultative vote on the Compensation System of Novartis. This vote takes place at least every third Annual General Meeting.

# Role of the Compensation Committee independent advisors

The Compensation Committee used Frederic W. Cook & Co, Inc., as its independent external compensation advisor for 2012. The advisor to the Compensation Committee is hired directly by the Compensation Committee, is independent of management and does not perform any other consulting work for Novartis. The key task of the advisor is to assist the Compensation Committee in ensuring that the Novartis compensation policies and plans are competitive, correspond to market practice, and are in line with our compensation principles.

The Compensation Committee enters into a consulting agreement with its independent advisor on an annual basis. In determining whether or not to renew the engagement with the advisor, the Compensation Committee evaluates the quality of the consulting service and the benefits of rotating advisors. In addition, the Compensation Committee assesses on an annual basis the projected scope of work for the coming year.

The Compensation Committee determined that the advisor is free of any relationship that would impair professional and objective judgment and advice to the Compensation Committee, and has never been hired for work by the management of Novartis.

### Clawback

Any incentive compensation paid to senior executives, including members of the Executive Committee, is subject to "clawback." This means that Novartis may choose not to pay future incentive compensation or seek to recover incentive compensation where the payout has been proven to conflict with internal management standards (including company policies and Novartis Values and Behaviors), accounting policies or a violation of law.

#### **Share ownership Requirements**

In line with our equity ownership principle, key executives are required to own at least a certain multiple of their annual base salary in Novartis shares or share options. The CEO is required to own Novartis equity worth 5 times, the members of the Executive Committee 3 times, and other key executives, 1 to 2 times (position-specific) their respective base compensation within three years of hire or promotion. In the event of a substantial drop in the share price, the Board of Directors may, at its discretion, extend that time period.

CEO	$5 \times \text{base salary}$
Members of the Executive Committee	$3 \times \text{base salary}$
Selected key executives	$1 \times \text{ or } 2 \times \text{ base salary}$

The determination of equity amounts against the share ownership requirements includes vested and unvested shares or ADSs acquired under the Novartis compensation plans, as well as RSUs, with the exception of unvested matching RSUs from leveraged share savings plans and unvested RSUs from the Long-Term Performance Plan. In addition, it includes other shares as well as vested options on Novartis shares or ADSs that are owned directly or indirectly by "persons closely linked" (1).

The Compensation Committee reviews compliance with the share ownership guideline on an annual basis.

## RISK MANAGEMENT

We believe that our compensation system encourages performance, loyalty and entrepreneurship, and creates sustainable value that is in the interest of Novartis and our shareholders. However, shareholders also expect that risks are appropriately managed. At Novartis, appropriate objective setting combined with proper incentive-plan design and rigorous safeguard measures allow our leaders and associates to focus on long-term value creation.

The goal of our compensation system is to encourage high performance and entrepreneurship, but not to reward inappropriate or excessive risk taking or short-term profit maximization at the expense of the long-term health of Novartis. The following characteristics of our compensation system foster a culture of entrepreneurial risk management:

Novartis Values and Behaviors: Compliance and ethical conduct are integral factors considered in all regular performance reviews, setting clear behavioral boundaries.

People Performance Management Process: A rigorous performance management system is in place based on agreed-upon objectives, values and behaviors reflecting compliance and meritocracy.

Balanced Scorecard Approach to Performance-based Incentives: The annual and long-term incentive compensation plans are not overly focused on any single measure of performance. Instead, financial objectives include net sales, operating income, free cash flow as a percentage of sales, and Novartis Economic Value Added (NVA). Non-financial objectives emphasize the

"Persons closely linked" are (i) their spouse, (ii) their children below age 18, (iii) any legal entities that they own or otherwise control, and (iv) any legal or natural person who is acting as their fiduciary.

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achievement of strategic and leadership objectives, and managing people, but also innovation as well as process and productivity improvement. Under the incentive plans, performance multipliers may not exceed 200% of target.

Balanced Mix of Compensation Elements and Performance Measures: The target compensation mix is not overly weighted toward annual incentive awards but represents a combination of cash and long-term share-based compensation vesting over three years.

Performance Period and Vesting Schedules: For long-term incentives, performance period and vesting schedules overlap, reducing the motivation to maximize performance in any one period. The equity awarded under the Equity Plan "Select" vests after a period of three years. The Long-Term Performance Plan is an equity plan based on a three-year performance period.

Clawback: We implemented "clawback" provisions in individual employment contracts of all members of the Executive Committee as well as in most incentive plans, and award letters to associates (see "Corporate Governance Clawback").

No Severance Payments or Change-of-Control Clauses: Employment contracts for members of the Executive Committee provide a notice period of 12 months and contain no change-of-control clauses or severance provisions (i.e. agreements concerning special notice periods, longer-term contracts, "golden parachutes," waiver of lock-up periods for equities and bonds, shorter vesting periods and additional contributions to occupational pension schemes).

Share Ownership Requirements: Members of the Executive Committee, as well as selected key executives are required to own a certain multiple of their annual base salary in Novartis shares or share options (see "Compensation Governance Share Ownership Requirements" on previous page).

### COMPENSATION OF THE BOARD OF DIRECTORS

### Philosophy For the Board of Directors compensation

Today, the members of boards of directors of global companies face increasing responsibilities and have to deal with issues that require ever higher levels of expertise and engagement. As a global healthcare company, Novartis shareholders have elected members of the Board of Directors who bring these required skills. Novartis has set the compensation for the members of the Board of Directors at a level that allows for the attraction and retention of high-caliber individuals with global experience. The members of its Board of Directors do not receive variable compensation, underscoring their focus on long-term corporate strategy, supervision and governance.

Compensation Structure

	Board
	compensation
Fixed compensation	Yes
Variable compensation	No

## Compensation of the members of the Board of Directors

#### Description

The Board of Directors determines the compensation of its members, other than the Chairman, each year, based on a proposal by the Compensation Committee and advice from its independent advisors.

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The compensation of the Chairman is based on a contract, which provides Dr. Daniel Vasella with a fixed remuneration of CHF 12.4 million, indexed to the average compensation increase for associates based in Switzerland. The Board acknowledges that the compensation of the Chairman reflects his exceptional experience and significant on-going contribution to building the Group, representing our interests in the global business community and delivering sustainable value for our shareholders. One third of his total compensation is paid out in monthly cash installments; the remaining two-thirds are in the form of unrestricted Novartis shares that are granted to him each year at the closing market price of the underlying share at the end of the day at grant date, in 2012 on January 19, 2012.

Following his tenure as Chairman, Dr. Vasella agreed to continue to make available his know-how to Novartis and to refrain from activities that compete with any business of Novartis for a multi-year period. Dr. Vasella will receive fair market compensation in return for his services and for complying with the restriction not to compete. Dr. Vasella carries forward tradable options, shares and benefits (including pension) as a result of his 14-year tenure as our CEO. In his current capacity he receives no variable compensation, tradable options or equity other than the shares that are part of his remuneration as Chairman.

The other members of the Board of Directors receive, in one installment, an annual fixed Board membership fee and additional fees for committee chairmanships, committee memberships, and other functions to compensate for their increased responsibilities and engagements. They do not receive additional fees for attending meetings. The annual fees cover the period from the Annual General Meeting of the year of disclosure to the next Annual General Meeting. These members of the Board of Directors are paid in unrestricted shares for at least 50% of their fees. If one of these Board of Directors members does not elect for a full grant in shares, the remaining part of the fee is paid in cash at the time the shares are delivered. The fees shown in the attached table reflects the full amount paid in cash or delivered as shares in the given year. With the exception of the Chairman, they do not have pension benefits. Members of the Board of Directors do not receive share options. The fee rates for Board membership and functional roles of other members of the Board of Directors are as follows:

### **Board Member Annual Fee Rates (Excl. Chairman)**

	Annual fee (CHF)
Board membership	350,000
Chairman's Committee membership	150,000
Audit and Compliance Committee membership	100,000
Other Board Committee membership	50,000
Vice chairmanship of the Board of Directors	50,000
Board Committee chairmanship (except for ACC)	10,000
Audit and Compliance Committee chairmanship	20,000
Delegated board membership <sup>(1)</sup>	125,000

(1)

The Board of Directors has delegated Rolf M. Zinkernagel to the Scientific Advisory Board of the Novartis Institute for Tropical Diseases (NITD). The Board of Directors has delegated both Rolf M. Zinkernagel and William Brody to the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF).

### Benchmarking of the Compensation of the Members of the Board of Directors

The level of compensation for the members of the Board of Directors is set based on benchmarks that include the remuneration of members of board of directors of comparable healthcare companies (see also the list of benchmark companies under "Compensation of Executives and other associates") and selected leading Swiss companies (i.e. UBS, Nestlé and Credit Suisse).

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(3)

(5)

(6)

(7)

(8)

# **Board Member Compensation in 2012**<sup>(1)</sup>

			Audit and			orporate vernance and Delega	Annual cash t <b>ed</b> mpensation	Shares (Market value)		Other	Total (CHF)
		VicChairma <b>Co</b> h <b>p</b> irnCommitt@o	•		•			(CHF) (B) <sup>(2)</sup>	Shares (Number)	(CHF) (C)	(A)+(B) +(C)
Daniel Vasella	Chair	•	(3)	(3)	(3)	(3)	4,110,750	8,241,815	152,063	715,027(4)	13,067,592
Ulrich Lehner			(2)	(=)	(=)	Chair	405,000	405,037	7,473	43,070(5)	853,107
Dimitri Azar							140,000	210,025	3,875		350,025
William Brody(6	5)						262,500	262,545	4,844		525,045
Srikant Datar			Chair				360,000	360,051	6,643		720,051
Ann Fudge							225,000	225,038	4,152		450,038
Pierre Landolt(7)	)							400,050	7,381	23,977(5)	424,027
Enrico Vanni					Chair		255,000	255,011	4,705	30,150(5)	540,161
Andreas von Planta				Chair			280,000	280,051	5,167	29,023(5)	589,074
Wendelin									2,201	=>,===(5)	
Wiedeking								500,049	9,226	29,607(5)	529,656
Marjorie M.T. Yang							200,000	200,052	3,691	24,177(5)	424,229
Rolf M.											
Zinkernagel <sup>(8)</sup>							325,000	325,037	5,997	34,383(5)	684,420
Total							6,563,250	11,664,761	215,217	929,414	19,157,425

Does not include reimbursement for travel and other necessary business expenses incurred in the performance of their services as these are not compensation.

# Shares and share Options Owned by members of the Board of Directors

Shareholders want Board members to align their interests with the rest of the shareholders. Among other requirements, the members of the Board of Directors are thus required to own at least 5,000 Novartis shares within three years after joining the Board of Directors. As of December 31, 2012, all members of the Board of Directors who have served at least three years on the Board of Directors have complied with the share ownership guidelines.

The last year in which Novartis granted share options to non-executive members of the Board of Directors was 2002. The total number of vested and unvested Novartis shares and share options owned by members of the Board of Directors and "persons closely linked" to them as of

The value of the shares reflected in this column has been calculated based on market value of the shares at grant date. All shares were granted as per January 19, 2012 against the prevailing share price of CHF 54.20.

Daniel Vasella attended the meetings of these Committees as a guest without voting rights.

<sup>(4)</sup> Includes inter alia social security costs due by the individual and paid by the company, pension and life insurance.

Includes social security costs due by the individual and paid by the company.

The Board of Directors has delegated William Brody to the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF).

According to Pierre Landolt, the Sandoz Family Foundation is the economic beneficiary of the compensation.

The Board of Directors has delegated Rolf M. Zinkernagel to the Scientific Advisory Board of the Novartis Institute for Tropical Diseases (NITD) and to the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF).

January 17, 2013, is shown in the following tables.

(1)

As of January 17, 2013, none of the members of the Board of Directors together with "persons closely linked" to them owned 1% or more of the outstanding shares of Novartis, either directly or through share options.

"Persons closely linked" are (i) their spouse, (ii) their children below age 18, (iii) any legal entities that they own or otherwise control, and (iv) any legal or natural person who is acting as their fiduciary.

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# Shares and Share Options Owned by Board Members (1)

	Number of shares <sup>(2)</sup>	Number of share options <sup>(3)</sup>
Daniel Vasella	3,170,729	1,633,290(4)
Ulrich Lehner	34,363	
Dimitri Azar	5,743	
William Brody	18,420	
Srikant Datar	31,080	
Ann Fudge	13,769	
Pierre Landolt <sup>(5)</sup>	52,356	
Enrico Vanni	12,501	
Andreas von Planta	121,334	
Wendelin Wiedeking	260,286	
Marjorie M.T. Yang	18,000	
Rolf M. Zinkernagel	45,948	
_		
Total	3,784,529	1,633,290

# Loans to members of the Board of Directors

No loans were granted to current or former members of the Board of Directors during 2012. No such loans were outstanding as of December 31, 2012.

## Other payments to members of the Board of Directors

During 2012, no payments (or waivers of claims) other than those set out in the Board Member Compensation table on the previous page (including its footnotes) were made to current members of the Board of Directors or to "persons closely linked" to them (see definition under "Compensation of the Board of Directors").

### Payments to former members of the Board of Directors

During 2012, no payments (or waivers of claims) were made to former Board members or to "persons closely linked" to them (see definition under "Compensation of the Board of Directors" Shares and Share Options Owned by Members of the Board of Directors"), except for an amount of CHF 62,346 that was paid to the Honorary Chairman.

# Note 27 to the Group's audited consolidated financial statements

<sup>(1)</sup>Includes holdings of "persons closely linked" to Board members (see definition under Share and Share Options owned by Members of the Board of Directors).

<sup>(2)</sup> Each share provides entitlement to one vote.

<sup>(3)
2002</sup> was the last year during which Novartis granted share options to non-executive Board members. All these options have expired in 2011.

<sup>(4)</sup> Includes options awarded during Daniel Vasella's tenure as Chairman and CEO.

<sup>(5)</sup>According to Pierre Landolt, the Sandoz Family Foundation is the economic beneficiary of all shares.

The total expense for the year for the compensation awarded to the members of the Board of Directors and the members of the Executive Committee using IFRS measurement rules is presented in note 27 to the Group's audited consolidated financial statements.

### Item 6.C Board Practices

Novartis strives to create sustainable value. Our corporate governance framework is designed to support this. While it complies with all applicable laws and implements best corporate governance standards, it is tailor-made for Novartis.

# INTRODUCTION

The corporate governance framework of Novartis reflects a system of checks and balances between the powers of the shareholders, the Board of Directors and the management with the goal to safeguard the interests of Novartis and its shareholders while creating sustainable value.

Since the creation of Novartis in 1996, the Board of Directors has continuously improved the corporate governance framework of Novartis by proactively implementing emerging best corporate governance standards long before these were embedded in the Swiss Code of Best Practice for Corporate Governance ("the Swiss Code") or in the law.

In 1999, Novartis established the new position of Lead Director as a check and balance following the election of Chief Executive Officer Daniel Vasella, M.D., to the additional post of Chairman. Moreover, three new Board committees the Compensation Committee, the Audit and Compliance Committee and the Corporate Governance and Nomination Committee were created, composed exclusively of independent Board members.

In 2002, five years before legislation came into force in 2007, requiring companies to disclose the total compensation of their executive management group as well as the highest compensation attributed to a member of the executive management, Novartis had already implemented even more rigorous disclosure standards by reporting the individual annual compensation of all members of the Executive Committee.

In 2004, two years earlier than required for non-US corporations, Novartis complied with the challenging certification requirements under the US Sarbanes-Oxley Act, in particular Section 404 of this Act.

In 2009, the Board of Directors established a new Risk Committee that oversees the Group's enterprise risk management, strengthening the Board of Directors' supervisory function over management in this critical area. While fostering a culture of risk-adjusted decision making, the Risk Committee ensures that reasonable risk-taking and innovation are not constrained.

In 2010, the Chairman and CEO functions were separated. In addition several emerging best corporate governance standards were proactively implemented, including the introduction of a "say-on-pay" shareholder vote, and making changes to the executive compensation system to further strengthen the alignment of incentives with the long-term success of Novartis and a number of new disclosures, including on qualifications of Board members.

In 2011, the first "say-on-pay" vote was held, where the shareholders endorsed the compensation system of Novartis.

Novartis evaluates emerging best governance standards and adopts those that are found to be appropriate for Novartis. These standards are then tailored to Novartis, its business, management, stakeholders and shareholders with a view to create a corporate governance regime that supports the creation of sustainable value. This cannot be achieved by implementing corporate governance standards "as is" ("one size fits all approach") and becomes impossible if corporate governance standards (embedded in corporate governance codes) are converted into binding, "one size fits all" rules as is currently contemplated in Switzerland.

In Switzerland, there will be a popular vote on March 3, 2013, on the so-called "Minder Initiative". The Swiss voters will de facto have to choose between the Minder Initiative and the indirect counter-proposal to this initiative proposed by Parliament. The latter would likely enter into force, if the Minder

Initiative were defeated by the voters. Both proposals include binding shareholder votes on the compensation system and on Board and executive compensation, a ban or binding shareholder approval of certain extraordinary payments (such as "payments in advance" or "golden parachutes"), yearly re-election of all board members, and election of the Chairman by the shareholders.

However, while the Minder Initiative (that claims to strengthen shareholder rights) limits shareholder rights by mandatory rules that the shareholders cannot change, the indirect counter-proposal, while also shifting rights from the boards to the shareholders, does not patronize the shareholders as the Minder Initiative does, as it allows, for example, the shareholders to decide whether their vote on executive compensation shall be binding or non-binding or whether they want to elect the Chairman or not. Moreover, it does not contain certain additional rules as proposed under the Minder Initiative, such as an obligation of all pension plans to vote all their shares (which in practice would almost be impossible to do, except if pension plans "blindly" followed the voting recommendation of proxy advisory firms, making such firm de facto "super-shareholders"), and criminal sanctions (imprisonment of up to three years) for violations of the Minder rules. Therefore, the indirect counter-proposal is the better choice for shareholders. It offers them the same additional rights as the Minder Initiative but does not limit their choices. This also applies to Switzerland as the Minder Initiative would substantially damage the international competitiveness of Switzerland and of Swiss based companies. For example: A binding shareholder vote on executive compensation would make it difficult for Swiss based companies to hire top managers, who would not know when they sign an employment contract whether such contract could be honored by their employer. Moreover, while the indirect counter-proposal could be implemented rapidly, the wording of the Minder Initiative is too sketchy and imprecise to allow a rapid implementation.

Outside of Switzerland, we note an encouraging development in that regulators start to acknowledge and seem to become willing to regulate many corporate governance issues that have been highlighted by issuers for a long time but did not make it "on the corporate governance agenda" yet: The US Securities Exchange Commission in its "Concept Release on the U.S. Proxy System" and, the European Commission in its green paper entitled "The EU Corporate Governance Framework" have noted a number of such issues, including deficiencies in the proxy system, potential conflicts of interest and a lack of accuracy and transparency of proxy advisory firms, and what the European Commission called "inappropriate short-termism among investors."

On that last point, we note that in July 2012 John Kay, an economics professor at the London School of Economics, issued a report on the UK equity markets and long-term decision making, which had been commissioned by the UK Government. Kay's principal conclusion is that institutional investors focus too much on short-term profits. This may lead investors to not support corporate strategies designed to achieve long-term growth and to support activist hedge funds that want to pressure corporations in taking actions to increase short-term profits to the detriment of the long-term prospects of the company.

Kay proposes, among other points, that incentives of asset managers should encourage them to hold portfolios judged on the basis of the long-term absolute performance of companies, that misaligned incentives in the remuneration practices of both company executives and asset managers should be eliminated, that investment costs and stock lending practices should be disclosed, that the duty of Board members is directed to their company and not to its share price, and that companies should aim to develop relationships with investors rather than with 'the market'.

At the heart of good corporate governance lies a strong board of directors, which represents the interests of the shareholders and other stakeholders, and the professionalism and integrity of management, creating the foundation for sustainable value. While the size, composition and structure of the board of directors are easy to describe and can be easily checked from the outside, it is difficult to demonstrate that the core processes, like information flow and decision making, are state-of-the-art. It is even more difficult, if not impossible, to describe the prevailing board culture, although the latter is essential for its effective function. Novartis aims to foster an atmosphere in which Board members can pose challenging questions, voice dissenting views and secure access to independent information through

extensive contacts with senior Novartis executives inside and outside the boardroom. Diversity of a board of directors is a critical success factor for its work. The Novartis Board of Directors today is diverse in terms of education, experience, geographical origin and interpersonal skills.

# SUMMARY OF OUR CORPORATE GOVERNANCE REGIME

# **Leadership Structure**

Separate Chairman and CEO

# **Board Governance**

## Structure

Independence: All Board members except Dr. Vasella, are independent. Dr. Vasella will be independent as from February 1, 2013.

Board Committees: The Board has delegated certain of its duties to five Board committees:

Chairman's Committee

Audit and Compliance Committee

Corporate Governance and Nomination Committee

Compensation Committee

Risk Committee

# Composition

The Novartis Board of Directors is diverse in terms of education, experience, geographical origin and interpersonal skills. The biographies of the Board members (pages 199 204) set out their particular qualifications.

#### Processes

The processes of the Board have a decisive influence on the effectiveness of the Board. The Board has implemented best practices for all such processes. Important elements include the agenda of Board meetings (making sure that the Board deals with all important topics), information of the Board (ensuring that the Board receives sufficient information from management to perform its supervisory duty and to make decisions that are reserved for the Board), and Board room behavior (ensuring an efficient and balanced decision making process).

#### **Shareholder Rights**

Each share registered entitles the holder to one vote at General Meetings. The General Meeting passes resolutions and elections with the absolute majority of the votes represented at the meeting: The approval of two-thirds of the votes represented at the meeting is required by law for certain important resolutions.

Shareholders with 10% of the share capital may request an extraordinary General Meeting of shareholders and shareholders having shares with an aggregate nominal value of CHF 1 million can put items on the agenda of a General Meeting of shareholders.

Shareholders have the right to receive dividends, appoint proxies, and hold such other rights as are granted under Swiss Law.

Only shareholders registered in the Novartis share register may exercise their voting rights. The registration does not affect the tradability of Novartis shares.

Shareholders with shares in excess of 2% of the registered share capital that want to vote also those shares exceeding the 2% threshold need an approval from the Board. The purpose of this approval is to prevent that a minority shareholder can dominate the General Meeting to the disadvantage of the majority of the shareholders. This is necessary given that many shareholder do not register their shares and can therefore not vote their shares, and because shareholder representation at General Meetings has traditionally been low in Switzerland.

### OUR CORPORATE GOVERNANCE FRAMEWORK

# **Laws and Regulations**

Novartis is subject to the laws of Switzerland, in particular Swiss company and securities laws, and to the securities laws of the United States as applicable to foreign private issuers of securities.

In addition, Novartis is subject to the rules of the Swiss Stock Exchange (SIX Swiss Exchange), including the Directive on Information relating to Corporate Governance.

Novartis is also subject to the rules of the New York Stock Exchange (NYSE) as applicable to foreign private issuers of securities. The NYSE requires Novartis to describe any material ways in which its corporate governance differs from that of domestic US companies listed on the NYSE. These differences are:

shareholders of Novartis do not receive written reports from committees of the Board of Directors;

the external auditors are appointed by the shareholders at the Annual General Meeting, as opposed to being appointed by the Audit and Compliance Committee;

while the shareholders cannot vote on all equity-compensation plans, they are entitled to hold a consultative vote on the compensation system of Novartis. The vote takes place before every significant change to the compensation system, but at least every third Annual General Meeting;

the Board of Directors has set up a separate Risk Committee that is responsible for risk oversight, as opposed to delegating this responsibility to the Audit and Compliance Committee;

the Chairman of the Board of Directors and the Audit and Compliance Committee share responsibility for and authority to supervise the internal audit function; and

the full Board of Directors has responsibility for setting the objectives relevant to the compensation of the Chief Executive Officer, and for the evaluation of the performance of the Chief Executive Officer.

### **Swiss Code of Best Practice for Corporate Governance**

Novartis applies the Swiss Code of Best Practice for Corporate Governance.

## **Novartis Corporate Governance Standards**

Novartis has incorporated the corporate governance standards described above into the Articles of Incorporation and the Regulations of the Board of Directors, its Committees and the Executive Committee (www.novartis.com/corporate-governance).

The Corporate Governance and Nomination Committee regularly reviews these standards and principles in the light of prevailing best practices and makes recommendations for improvements of the corporate governance framework of Novartis for consideration by the full Board of Directors.

Additional corporate governance information can be found on the Novartis website: http://www.novartis.com/corporate-governance

Printed copies of the Novartis Articles of Incorporation, Regulations of the Board and Charters of Board Committees can be obtained by writing to: Novartis AG, Attn: Corporate Secretary, Lichtstrasse 35, CH-4056 Basel, Switzerland.

# **OUR SHAREHOLDERS**

### **Shares**

#### Share Capital of Novartis AG

The share capital of Novartis AG is CHF 1,353,096,500 fully paid-in and divided into 2,706,193,000 registered shares, each with a nominal value of CHF 0.50. Novartis has neither authorized nor conditional capital. There are no preferential voting shares; all shares have equal voting rights. No participation certificates, non-voting equity securities (Genussscheine) or profit-sharing certificates have been issued.

Novartis shares are listed and traded on the SIX Swiss Exchange (Valor No. 001200526, ISIN CH0012005267, symbol: NOVN) as well as on the NYSE in the form of American Depositary Receipts (ADRs) representing Novartis American Depositary Shares (ADSs) (Valor No. 567514, ISIN US66987V1098, symbol: NVS).

The holder of an ADS has the rights enumerated in the Deposit Agreement (such as the right to vote and to receive a dividend). The ADS depositary of Novartis, JPMorgan Chase Bank, New York, holding the Novartis shares underlying the ADSs, is registered as shareholder in the share register of Novartis. An ADS is not a Novartis share and an ADS holder is not a Novartis shareholder. ADS holders exercise their voting rights by instructing the depositary to exercise their voting rights. Each ADS represents one Novartis share.

### Share Repurchase Programs

Novartis began repurchasing its shares in 1999. Since then, five share repurchase programs have been completed with the repurchase of shares worth CHF 19 billion. Shares repurchased under the first program were not cancelled. However, shares repurchased under the other four programs were cancelled. At the Annual General Meeting in February 2008, shareholders authorized the Board of Directors to launch a sixth program to repurchase shares up to a maximum amount of CHF 10 billion via a second trading line on the SIX Swiss Exchange. In 2008, a total of six million shares were repurchased at an average price of CHF 49.42 per share and cancelled. The share repurchase program was suspended in April 2008 in favor of debt repayment. In December 2010, the Board of Directors announced the reactivation of the share repurchase program to minimize dilution to existing Novartis shareholders in connection with the proposed merger of Alcon, Inc. into Novartis. In 2010, no shares were repurchased under the share repurchase program. In 2011, 39,430,000 shares were repurchased under the share repurchase program. In 2012, no shares were repurchased under the share repurchase program.

### Changes in Share Capital

During the last three years there were the following changes to the share capital of Novartis:

In 2011, for the purpose of completing the merger of Alcon, Inc. into Novartis AG, the share capital was increased by CHF 54 million, from CHF 1,318,811,500 to CHF 1,372,811,500, through the issuance of 108,000,000 fully paid-in registered shares with a nominal value of CHF 0.50 each.

In 2012, Novartis reduced its share capital by CHF 19,715 million, from CHF 1,372,811,500 to CHF 1,353,096,500 by cancelling 39.43 million shares repurchased on the second trading line during 2011.

# **Capital Changes**

Number of shares					
	As of	Changes	As of	Changes	
Year	January 1	in shares	December 31	in CHF	
2010	2,637,623,000		2,637,623,000		
2011	2,637,623,000	108,000,000	2,745,623,000	54,000,000	
2012	2.745.623.000	(39.430.000)	2.706.193.000	(19.715.000)	

### Convertible or Exchangeable Securities

Novartis has not issued convertible or exchangeable bonds, warrants, options or other securities granting rights to Novartis shares, other than options granted to associates as an element of compensation.

# **Shareholdings**

# Significant Shareholders

According to the share register, as of December 31, 2012, the following registered shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:<sup>(1)</sup>

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 4.0%; and Emasan AG, with its registered office in Basel, Switzerland, holding 3.3%;

Nominees: JPMorgan Chase Bank, New York, holding 11.4%; Nortrust Nominees, London, holding 3.3%; and The Bank of New York Mellon, New York, holding 5.0% through its nominees, Mellon Bank, Everett, (3.3%) and The Bank of New York Mellon, Brussels, Belgium, (1.7%); and

ADS depositary: JPMorgan Chase Bank, New York, holding 11.7%.

 $\hbox{ Excluding 4.09\% of the share capital held by Novartis AG, together with Novartis affiliates, as treasury shares. } \\$ 

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According to a disclosure notification filed with Novartis AG, Norges Bank (Central Bank of Norway), Oslo, Norway, held 2.3% of the share capital of Novartis AG as of December 31, 2012.

According to disclosure notifications filed with Novartis AG and the SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2012:

Capital Group Companies, Inc., Los Angeles, USA

BlackRock, Inc., New York, USA

Disclosure notifications pertaining to shareholdings in Novartis AG that were filed with Novartis AG and the SIX Swiss Exchange are published on the latter's electronic publication platform, and can be accessed via the database search page:

http://www.six-exchange-regulation.com/obligations/disclosure/ major\_shareholders\_en.html

Novartis has not entered into any agreement with any shareholder regarding the voting or holding of Novartis shares.

# Cross Shareholdings

Novartis has no cross shareholdings in excess of 5% of capital or voting rights with any other company.

### Distribution of Novartis Shares

The information in the following tables relates only to registered shareholders and does not include holders of unregistered shares. Also, the information provided in the tables below cannot be assumed to be representative of the entire Novartis investor base since nominees and JPMorgan Chase Bank, as ADS depositary, are registered as shareholders for a large number of beneficial owners.

As of December 31, 2012, Novartis had approximately 161000 registered shareholders.

The following table provides information about the distribution of registered shareholders by number of shares held:

### **Number of Shares Held**

	Number of registered	% of registered
As of December 31, 2012	shareholders	share capital
1-100	20,133	0.05
101-1,000	95,483	1.58
1,001-10,000	40,581	4.23
10,001-100,000	3,740	3.57
100,001-1,000,000	488	5.23
1,000,001-5,000,000	74	6.06
5,000,001 or more <sup>(1)</sup>	34	54.01
Total registered shareholders/shares	160,533	74.73
Unregistered shares		25.27
Total		100.00

Including significant registered shareholders as listed above

The following table provides information about distribution of registered shareholders by type:

# Registered Shareholders by Type

As of December 31, 2012	Shareholders in %	Shares in %
Individual shareholders	96.07	12.08
Legal entities	3.84	37.26
Nominees, fiduciaries and ADS depositary	0.09	50.66
Total	100.00	100.00

The following table provides information about registered shareholders by country:

### **Registered Shareholders by Country**

As of December 31, 2012	Shareholders in %	Shares in %
France	2.84	1.31
Germany	4.56	3.55
Switzerland <sup>(1)</sup>	89.15	42.13
United Kingdom	0.51	2.75
United States	0.32	46.24
Other countries	2.62	4.02
Total	100.00	100.00

Excluding 4.09% of the share capital held by Novartis AG, together with Novartis affiliates, as treasury shares

## **SHAREHOLDER RIGHTS**

(1)

Right to Vote ("One Share, One Vote")

Each share registered with the right to vote entitles the holder to one vote at General Meetings.

ADS holders may vote by instructing JPMorgan Chase Bank, the ADS depositary, to exercise the voting rights attached to the registered shares underlying the ADSs. JPMorgan Chase Bank exercises the voting rights for registered shares underlying ADSs for which no voting instructions have been given by providing a discretionary proxy to the independent proxy (unabhängiger Stimmrechtsvertreter) appointed by Novartis pursuant to Swiss law.

# Resolutions and Elections at General Meetings

The General Meeting passes resolutions and elections with the absolute majority of the votes represented at the meeting. However, under the Articles of Incorporation (www.novartis.com/corporate-governance) the approval of two-thirds of the votes represented at the meeting is required for:

An alteration of the purpose of Novartis AG;

The creation of shares with increased voting powers;

An implementation of restrictions on the transfer of registered shares and the removal of such restrictions;

An authorized or conditional increase of the share capital;

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An increase of the share capital out of equity, by contribution in kind, for the purpose of an acquisition of property, or the grant of special rights;

A restriction or suspension of rights or options to subscribe;

A change of location of the registered office of Novartis AG; or

The dissolution of Novartis AG.

In addition, the law provides for a special quorum also for other re-solutions, such as, for example, for a merger or spin-off.

### Other Shareholder Rights

Shareholders representing at least 10% of the share capital may request that an extraordinary General Meeting of shareholders be convened. Shareholders representing shares with an aggregate nominal value of at least CHF 1 million may request that an item be included in the agenda of a General Meeting of shareholders. Such requests must be made in writing at least 45 days before the date of the General Meeting, specify the item to be included in the agenda and contain the proposal on which the shareholder requests a vote.

Shareholders have the right to receive dividends, appoint another shareholder, the corporate proxy, the independent proxy or a custody proxy as proxy and hold such other rights as are granted under Swiss Law.

#### **Shareholder Registration**

No restrictions apply on the transferability of Novartis shares. However, only shareholders registered in the Novartis share register may exercise their voting rights. In order to be registered, a shareholder must declare that he or she acquired the shares in his or her own name and for his or her own account. The Articles of Incorporation provide that the Board of Directors may register nominees with the right to vote. For restrictions on registration of nominees, please see below.

The Articles of Incorporation provide that no shareholder shall be registered with the right to vote for more than 2% of the registered share capital. The Board of Directors may, upon request, grant an exemption from this restriction. Exemptions are in force for the registered Significant Shareholders listed under Our Shareholders Shareholdings Significant Shareholders. In 2012, an exemption was requested and granted to Norges Bank (Central Bank of Norway), Oslo, Norway.

The same restrictions apply to holders of ADSs as those holding Novartis shares.

Given that shareholder representation at General Meetings has traditionally been low in Switzerland, Novartis considers the restriction on registration necessary to prevent a minority shareholder from dominating a General Meeting.

The Articles of Incorporation provide that no nominee shall be registered with the right to vote for more than 0.5% of the registered share capital. The Board of Directors may, upon request, grant an exemption from this restriction if the nominee discloses the names, addresses and the number of shares of the persons for whose account it holds 0.5% or more of the registered share capital. Exemptions are in force for the nominees listed under Our Shareholders Shareholdings Significant Shareholders.

The same restrictions apply to holders of ADSs as those holding Novartis shares.

The restrictions on registration contained in the Articles of Incorporation may only be removed by a resolution of the General Meeting of shareholders, with approval of at least two-thirds of the votes represented at the meeting.

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Shareholders, ADS holders or nominees that are linked to each other or act in concert to circumvent the restrictions on registration are treated as one person or nominee for the purposes of the restrictions on registration.

### **No Restriction on Trading of Shares**

The registration of shareholders in the Novartis share register or in the ADS register kept by JPMorgan Chase Bank does not affect the tradability of Novartis shares or ADSs. No restrictions are imposed by Novartis or JPMorgan Chase Bank on the trading of registered Novartis shares or ADSs. Registered Novartis shareholders or ADS holders may, therefore, purchase or sell their Novartis shares or ADSs at any time, including prior to a General Meeting regardless of the record date. The record date serves only to determine the right to vote at a General Meeting of Novartis.

#### **Change-of-Control Provisions**

### No Opting Up, No Opting Out

The Swiss Stock Exchange Act provides that anyone who, directly, indirectly or acting in concert with third parties, acquires equity securities exceeding 33<sup>1</sup>/<sub>3</sub>% of the voting rights of a company whether or not such rights are exercisable is required to make an offer to acquire all listed equity securities of that company. A company may raise this threshold to 49% of the voting rights ("opting up") or may, under certain circumstances, waive the threshold ("opting out"). Novartis has not adopted any such measures.

## Change-of-Control Clauses

There are no change-of-control clauses (including no "golden parachutes", special provisions on the cancellation of contractual arrangements, agreements concerning special notice periods or long-term contracts exceeding 12 months, waivers of lock-up periods for options, shorter vesting periods, and no additional contributions to pension funds) benefiting Board members. With respect to members of the Executive Committee, see below under Our Management Contracts with Members of the Executive Committee.

### OUR BOARD OF DIRECTORS

### **Election and Term of Office**

All Board members are elected individually.

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Board members are elected to terms of office of three years or less by shareholders at General Meetings. The terms of office among Board members are to be coordinated so that approximately one-third of all Board members are subject each year to re-election or election. Under Swiss law, a General Meeting of shareholders is entitled to remove any Board member at any time, regardless of his or her remaining term of office.

The average tenure of Board members is eight years and the average age is 62. A Board member must retire after reaching age 70. Under special circumstances, shareholders may grant an exemption from this rule and re-elect a Board member for additional terms of office of no more than three years at a time.

		Year	First election	Last election	End of current
Name	Nationality	of birth	at AGM	at AGM	Term
Daniel Vasella, M.D.	CH	1953	1996	2010	2013
Ulrich Lehner, Ph.D.	D	1946	2002	2011	2014
Dimitri Azar, M.D.	US	1959	2012		2015
William Brody, M.D.,					
Ph.D.	US	1944	2009	2012	2014
Srikant Datar, Ph.D.	US	1953	2003	2012	2015
Ann Fudge	US	1951	2008	2011	2014
Pierre Landolt, Ph.D.	CH	1947	1996	2011	2014
Enrico Vanni, Ph.D.	CH	1951	2011	2011	2014
Andreas von Planta, Ph.D.	CH	1955	2006	2012	2015
Dr. Ing. Wendelin					
Wiedeking	D	1952	2003	2012	2015
Marjorie M.T. Yang	CHN	1952	2007	2010	2013
Rolf M. Zinkernagel, M.D.	CH	1944	1999	2012	2014

# **Board Member Qualifications**

The Corporate Governance and Nomination Committee determines the criteria for the selection of the Board members and Board committee members. Factors considered include skills and knowledge, diversity of viewpoints, professional backgrounds and expertise, business and other experience relevant to the business of Novartis, the ability and willingness to commit adequate time and effort to Board and committee responsibilities, the extent to which personality, background, expertise, knowledge and experience will interact with other Board members to build an effective and complementary Board, and whether existing board memberships or other positions held by a candidate could lead to a conflict of interest.

The biographies of the Board members (pages 199 204) set out the particular qualifications that led the Board of Directors to conclude that a Board member is qualified to serve on the Board of Directors, creating a Board that today is diverse in terms of background, qualifications, interests and skills.

## **Board Diversity**

Diversity of a Board of Directors is a critical success factor for its effectiveness and, thus, when the Corporate Governance and Nomination Committee identifies new Board member candidates for the purpose of proposing these to the shareholders for election, to maintain or even improve diversity of the Board is an important criteria. The Board's aspiration is to have a diverse Board in all aspects of diversity. This includes diversity in terms of geographic origin, background, gender, race, faith, education, experience, viewpoint, interests and technical and interpersonal skills.

This has resulted in the Novartis Board being diverse in the above aspects.

# Role of the Board of Directors and the Board Committees

The Board of Directors is responsible for the overall direction and supervision of the management and holds the ultimate decision-making authority for Novartis AG, except for those decisions reserved to the shareholders.

The Board of Directors has delegated certain responsibilities to five committees: Chairman's Committee, Compensation Committee, Audit and Compliance Committee, Corporate Governance and Nomination Committee and Risk Committee as set out below (responsibilities described with the terms "overseeing" or "reviewing" are subject to final approval by the Board of Directors).

Responsibilities THE BOARD OF DIRECTORS	Membership comprises	Number of meetings held in 2012/ approximate average duration (hrs) of each meeting Attendance 9/8.5	Link
The primary responsibilities of the Board of Directors include:	Daniel Vasella	9	Articles of Incorporation of Novartis AG
Setting the strategic direction of the Group;	Ulrich Lehner	9	<u>r</u>
Determining the organizational structure and governance of the	Dimitri Azar <sup>(2)</sup>	7	Regulations of the Board of Directors, its
Group;	William Brody	9	Committees and the Executive Committee of
Appointing, overseeing and dismissing key executives and	Srikant Datar	9	Novartis AG (Board Regulations)
planning their succession;	Ann Fudge	9	, ,
Determining and overseeing the financial planning, accounting,	Pierre Landolt	8	http://www.novartis.com/corporate-governance
reporting and controlling;	Enrico Vanni	9	
Approving the annual financial statements and the corresponding	Andreas von Planta	9	
financial results releases; and	Wendelin Wiedeking	9	
Approving major transactions and investments.	Marjorie M.T. Yang	7	
	Rolf M. Zinkernagel	9	
THE CHAIRMAN'S COMMITTEE The primary responsibilities of this committee include:		5/2.5	
Commenting on significant matters before the Board of	Daniel Vasella	5	Charter of the Chairman's Committee
Directors makes a decision;	Srikant Datar	5	
Recommending key executive appointments to the Board of	Ulrich Lehner	5	http://www.novartis.com/corporate-governance
Directors;			
Dealing with Board matters arising in between Board meetings,			
including the taking of required preliminary actions; and			
Approving transactions and investments as delegated by the			
Board of Directors.	250		

The prima Oversee Supervis the extern sharehold Oversee compliand Approvi releases; Oversee procedure Oversee regulation The Audi	ary responsibilities of this committee include: using the internal auditors; using the external auditors and selecting and nominating and auditors for election by the meeting of the lers; using the accounting policies, financial controls and ce with accounting and internal control standards; using quarterly financial statements and financial results using internal control and compliance processes and les; and using compliance with laws and external and internal	Membership comprises Srikant Datar Ulrich Lehner <sup>(3)</sup> Enrico Vanni Andreas von Planta Wendelin Wiedeking	Number of meetings held in 2012/approximate average duration (hrs) of each meeting Attendance 6/3 6 6 6 6 5	Link Charter of the Audit and Compliance Committee http://www.novartis.com/corporate-governance
The prima Ensuring effective of Ensuring risk-adjus risk-takin Approvi Reviewi auditors the risks, the with risk implement	ary responsibilities of this committee include: g that Novartis has implemented an appropriate and risk management system and process; g that all necessary steps are taken to foster a culture of sted decision making without constraining reasonable g and innovation; ing guidelines and reviewing policies and processes; and ing with management, internal auditors and external he identification, prioritization and management of the accountabilities and roles of the functions involved management, the risk portfolio and the related actions nted by management. Committee has the authority to retain external tts and other advisors.	Andreas von Planta Srikant Datar Ann Fudge Ulrich Lehner Wendelin Wiedeking	4/2 4 4 4 4 4	Charter of the Risk Committee  http://www.novartis.com/corporate-governance
(1)	Chair Since February 2012			
(3)	Audit Committee Financial Expert as defined by the US	S Securities and Exchang 251	e Commission (SEC)	

Responsibilities	Membership comprises	Number of meetings held in 2012/ approximate average duration (hrs) of each meeting Attendance	Link
THE COMPENSATION COMMITTEE		6/2.5	
The primary responsibilities of this committee include:	Enrico Vanni	6	Charter of the Compensation Committee
Designing, reviewing and recommending to the Board compensation policies and programs;	William Brody Srikant Datar	6 6	http://www.novartis.com/]corporate-governance
Advising the Board on the compensation of the Board members;		6	nttp://www.novartis.com/jeorporate/governance
Approving the employment terms of key executives;	Marjorie M.T. Yang	4	
Deciding on the variable compensation of the Chief Executive			
Officer, the members of the Executive Committee and other key			
executives for the past year; and			
Deciding on the base salary and the total target compensation of the Chief Executive Officer, the members of the Executive			
Committee and other key executives for the coming year.			
The Compensation Committee has the authority to retain			
external consultants and other advisors.			
THE CORPORATE GOVERNANCE AND NOMINATION COMMITTEE		3/2	
The primary responsibilities of this committee include:	Ulrich Lehner	3	Charter of the Corporate Governance and
Designing, reviewing and recommending to the Board corporate	Ann Fudge	3	Nomination Committee
governance principles;	Pierre Landolt	3	
Reviewing on a regular basis the Articles of Incorporation with	Andreas von Planta	3	http://www.novartis.com/corporate-governance
a view to reinforcing shareholder rights; Reviewing on a regular basis the composition and size of the	Rolf M. Zinkernagel	3	
Board and its committees;			
Reviewing annually the independence status of each Board			
member;			
Reviewing directorships and agreements of board members for			
conflicts of interest and dealing with conflicts of interest;			
Identifying candidates for election as Board member;			
Assessing existing Board members and recommending to the Board whether they should stand for re-election;			
Preparing and reviewing the succession plan for the CEO; and			
Developing and reviewing an orientation program for new			
Board members and an ongoing education plan for existing			
Board members.			
The Corporate Governance and Nomination Committee has the authority to retain external consultants and other advisors.			
authority to retain external consultants and other advisors.			
(1)			
Chair			

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### The Functioning of the Board of Directors

The Novartis Board of Directors takes decisions as a whole, supported by its five Board committees (Chairman's Committee, Compensation Committee, Audit and Compliance Committee, Corporate Governance and Nomination Committee and Risk Committee). Each Board committee has a written charter outlining its duties and responsibilities and is led by a Chair elected by the Board of Directors.

The Board of Directors and its Board committees meet regularly throughout the year. The Chairs set the agendas of their meetings. Any Board member may request a Board meeting, a meeting of a Board committee or the inclusion of an item on the agenda of such meetings. Board members are provided, in advance of meetings, with materials intended to prepare them to discuss the items on the agenda.

# The Chairman

The Chairman provides leadership to the Board of Directors in its governance role, oversees that the strategy agreed by the Board of Directors is implemented by the Chief Executive Officer and his reports, provides support and advice to the Chief Executive Officer, reviews the yearly objectives and prepares the performance evaluation of the Chief Executive Officer before approval by and feed-back session with the Board of Directors, works closely with the Chief Executive Officer in nominating and evaluating members and permanent attendees of the Executive Committee and in establishing succession plans for key management positions, represents Novartis with stakeholders and oversees Internal Audit.

### **Meetings of the Board of Directors**

The Board of Directors has meetings with the members of the Executive Committee as well as private meetings without members of the Executive Committee.

Topics addressed in the meetings with the Executive Committee include strategy, business reviews and major projects, investments and transactions. Topics addressed in private meetings include performance evaluation of top management, succession planning and Board self-evaluation.

In 2012, there were nine meetings of the Board of Directors and three meetings of the independent Board members. Given that as of February 1, 2013 all Board members will be independent no meetings of the independent Board members, led by the Vice Chairman, will be held going forward.

# **Independence of Board Members**

The independence of Board members is a key corporate governance issue. Accordingly, Novartis established independence criteria that are intended to reflect international best-practice standards. These independence criteria (last revised on December 14, 2011) can be found on the Novartis website:

www.novartis.com/investors/governance-documents.shtml

The Corporate Governance and Nomination Committee annually submits to the Board of Directors a proposal concerning the determination of the independence of each Board member. For this assessment, the Committee considers all relevant facts and circumstances of which it is aware.

In its meeting of December 12, 2012, the Board of Directors determined that all of its members except Dr. Vasella are independent. Dr. Vasella will be independent as from February 1, 2013, when the three year look-back period for having been an employee of Novartis will end (Dr. Vasella was until January 31, 2010 also the Chief Executive Officer). The Board of Directors has delegated Rolf M. Zinkernagel, M.D., to the Scientific Advisory Board of the Novartis Institute for Tropical Diseases (NITD), and both Dr. Zinkernagel, M.D. and William Brody, M.D. to the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF). The Board of Directors concluded that

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these activities are supervisory and not consultatory in nature and do not affect Dr. Zinkernagel's or Dr. Brody's independence as a Board member.

### Relationship of Non-Executive Board Members with Novartis

With the exception of Dr. Vasella none of the Board members is or was a member of the management of Novartis AG or of any other Novartis Group company in the three financial years preceding 2012.

There are no significant business relationships of any Board member with Novartis AG or with any other Novartis Group company.

### Performance and Effectiveness Evaluation of the Board

#### **Process**

Every year the Board conducts an evaluation of its performance and effectiveness. The process is kicked-off by each Board member completing a questionnaire on the performance and effectiveness of the Board and of each Board committee of which he/she is a member. This is then the basis for a deep, qualitative review of the Board's performance. The review is led by the Chairman who holds individual discussions with each Board member, followed-up by discussions by the full Board and by each Board Committee. Identified gaps and shortcomings are recorded and related remediation actions are agreed.

On a regular basis this internal process is extended to cover individual Board member assessments and/or the process is conducted by an independent outside consultant.

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The performance review examines performance and effectiveness, strength and weaknesses, individual and for the full Board and each Board committee. The review includes composition, structure, processes, tasks and governance of the Board and its committees, effectiveness of meetings, behavior, team dynamics and interactions, quality of briefing materials and presentations, follow-up actions on decisions, relationship to senior management, and the role and leadership of the Chairman. The list of performance criteria is customized for each committee, addressing their specific tasks and responsibilities.

### Information and Control Systems of the Board of Directors vis-à-vis Management

### Information on the Management

The Board of Directors ensures that it receives sufficient information from the Executive Committee to perform its supervisory duty and to make decisions that are reserved for the Board of Directors. The authority of the Board of Directors to determine the compensation of the members of the Executive Committee is an important element to ensure the alignment of Executive Committee members with the interests of Novartis and its shareholders.

The Board of Directors obtains the information required to perform its duties through several means:

the Chief Executive Officer informs the Board regularly about current developments;

the minutes of Executive Committee meetings are made available to the Board members;

meetings or teleconferences are held as required between Board members and the Chief Executive Officer;

the Board of Directors regularly meets with all members of the Executive Committee;

the Board of Directors is updated in detail by each Division Head on a quarterly basis;

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by invitation, other members of management are invited to attend Board meetings to report on areas of the business within their responsibility; and

Board members are entitled to request information from members of the Executive Committee or any other Novartis associate, and may also visit any Novartis site.

#### **Board Committees**

Board committees regularly meet with management and, at times, outside consultants to review the business, better understand applicable laws and policies affecting the Group and support the Board of Directors and the management in meeting the requirements and expectations of stakeholders and shareholders.

In particular, the Chief Financial Officer, the Group General Counsel and representatives of the external auditors are invited to meetings of the Audit and Compliance Committee. Furthermore, the Heads of Internal Audit, Financial Reporting and Accounting, Compliance, Quality, as well as the Business Practices Officers, report on a regular basis to the Audit and Compliance Committee.

The Audit and Compliance Committee reviews financial reporting processes on behalf of the Board of Directors. For each quarterly and annual release of financial information, the Disclosure Review Committee reviews the release for accuracy and completeness of disclosures. The Disclosure Review Committee is chaired by the Chief Financial Officer and is attended by the Group General Counsel, the Heads of the Divisions, the Heads of Finance of the Divisions and the Heads of the following Corporate Functions: Treasury, Financial Reporting and Accounting, Internal Audit and Investor Relations. Decisions made by the Disclosure Review Committee are reviewed by the Audit and Compliance Committee before publication of the quarterly and annual releases.

The Risk Committee oversees the risk management system and processes, as well as reviews the risk portfolio of the Group to ensure appropriate and professional management of the risks. For this purpose the Corporate Risk Management function and the risk owners of the Divisions report on a regular basis to the Risk Committee. The Group General Counsel and the Head of Internal Audit are also invited to the meetings.

# Novartis Management Information System

Novartis produces comprehensive consolidated financial statements on a monthly basis for the total Group and its divisions. These are typically available within ten days of the end of the month and include the following:

consolidated income statement of the month, quarter-to-date and year-to-date in accordance with International Financial Reporting Standards (IFRS), as well as adjustments to arrive at Core results as defined by Novartis. The IFRS and Core figures are compared to the prior year period and targets in both USD and on a constant currency basis;

consolidated balance sheet as of the month end in accordance with IFRS in USD;

consolidated cash flow on a monthly, quarter-to-date and year-to-date basis in accordance with IFRS in USD; and

supplementary data on a monthly, quarterly and year-to-date basis such as free cash flow and gross and net liquidity, headcount, personnel costs, working capital, earnings per share and economic value added as defined by Novartis and on a USD basis where applicable.

The above information is made available to the members of the Board on a monthly basis. An analysis of the key deviations from prior year or target is also provided.

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The Board also receives on a quarterly basis an outlook of the full year results in accordance with IFRS and Core, together with related commentary prior to the release of the quarterly results.

On an annual basis, in the fourth quarter of the year, the Board receives and approves the operating and financial targets for the following year.

In the middle of the year, the Board also reviews and approves the Strategic Plan for the next five years and the consolidated income statement in USD in accordance with IFRS and Core (as defined by Novartis) contained in the Plan.

The Board does not have direct access to Novartis' financial and management reporting systems but can at any time request more detailed financial information on any aspect that is presented to it.

### Internal Audit

The Internal Audit function carries out operational and system audits in accordance with an audit plan approved by the Audit and Compliance Committee; assists organizational units in the accomplishment of objectives by providing an independent approach to the evaluation, improvement and effectiveness of their internal control framework; prepares reports regarding the audits it has performed; and reports actual or suspected irregularities to the Audit and Compliance Committee and the Chairman. The Audit and Compliance Committee regularly reviews the scope of Internal Audit, the audit plans and the results of the internal audits.

### Risk Management

The Corporate Risk Management function reports to the independent Risk Committee of the Board of Directors. The Compensation Committee works closely with the Risk Committee to ensure that the compensation system does not lead to excessive risk-taking by management (for details see our Compensation Report).

Organizational and process measures have been designed to identify and mitigate risks at an early stage. Organizationally, the individual divisions are responsible for risk and risk mitigation, with specialized corporate functions, such as Group Finance, Group Quality Operations, Corporate Health, Safety, Environment and Business Continuity, providing support and controlling the effectiveness of risk management by the Divisions in these respective areas.

## Relations with Shareholders

Communication with shareholders allows the shareholders to be better informed on Novartis' strategy, business operations and governance, and the Board to learn about expectations and concerns of the shareholders and to address these.

The CEO, with the investor relations team and supported by the Chairman, is responsible for ensuring effective communication with shareholders.

Novartis communicates with its shareholders through the Annual General Meeting, meetings with groups of shareholders or with individual shareholders, and through written or electronic communication with shareholders.

At the Annual General Meeting the Chairman and the Vice-Chairman, the members of the Executive Committee and representatives of the external auditors are present and can answer questions of shareholders. Meetings with shareholders may be attended by the Chairman, CEO, CFO, members of the Executive Committee and other members of senior management.

Topics discussed with shareholders include strategy, business performance and corporate governance.

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#### **OUR MANAGEMENT**

#### **Composition of the Executive Committee**

The Executive Committee is headed by the Chief Executive Officer. The members of the Executive Committee are appointed by the Board of Directors. The Chairman may appoint or remove non-voting Permanent Attendees to attend the meetings of the Executive Committee. As of December 31, 2012, there was 1 Permanent Attendee attending meetings of the Executive Committee.

The organizational structure and the details of the responsibility of the Executive Committee are set forth in the Board Regulations (www.novartis.com/corporate-governance).

The Board of Directors has not concluded any contracts with third parties to manage the business.

#### Role and Functioning of the Executive Committee

The Board of Directors has delegated to the Executive Committee the coordination of the Group's business operations. This includes:

Developing policies, strategies and strategic plans for approval by the Board of Directors and implementing those approved by the Board of Directors;

Submitting to the Board of Directors and its committees proposed changes in management positions of material significance, investments, financial measures, acquisitions or divestitures, contracts of material significance and budgets;

Preparing and submitting quarterly and annual reports to the Board of Directors or its committees;

Informing the Board of Directors of all matters of fundamental significance to the businesses;

Recruiting, appointing and promoting senior management;

Ensuring the efficient operation of the Group and achievement of optimized results;

Promoting an active internal and external communications policy; and

Dealing with any other matters as are delegated by the Board of Directors to the Executive Committee.

# **The Chief Executive Officer**

In addition to other duties that may be assigned by the Board of Directors, the Chief Executive Officer, supported by the Executive Committee, is responsible overall for the management and

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performance of the business, leads the Executive Committee, builds and maintains an effective executive team and represents Novartis with major customers, financial analysts, investors and with the media.

#### **Contracts With Members of the Executive Committee**

In accordance with good corporate governance, employment contracts with members of the Executive Committee do not contain unusually long notice periods, change-of-control clauses (including no "golden parachutes", special provisions on the cancellation of contractual arrangements, agreements concerning special notice periods or long-term contracts exceeding 12 months, waivers of lock-up periods for options, shorter vesting periods, and no additional contributions to pension funds) or severance payments.

#### **OUR INDEPENDENT EXTERNAL AUDITORS**

#### **Duration of the Mandate and Terms of Office**

Based on a recommendation by the Audit and Compliance Committee, the Board of Directors nominates an independent auditor for election at the Annual General Meeting. PricewaterhouseCoopers (PwC) assumed its existing auditing mandate for Novartis in 1996. Peter Kartscher, auditor in charge, and Michael P. Nelligan, global relationship partner, began serving in their respective roles in 2009. The Audit and Compliance Committee ensures that the auditor in charge is rotated at least every five years.

#### Information to the Board of Directors and the Audit and Compliance Committee

The independent auditor, PwC, is responsible for opining on whether the audited consolidated financial statements comply with International Financial Reporting Standards (IFRS) and Swiss law and whether the separate parent company financial statements of Novartis AG comply with Swiss law. Additionally, PwC is responsible for opining on the effectiveness of internal control over financial reporting.

The Audit and Compliance Committee, acting on behalf of the Board of Directors, is responsible for overseeing the activities of PwC. During 2012, the Audit and Compliance Committee held 6 meetings. At each of these meetings, PwC was invited to attend during the discussion of agenda items that dealt with accounting, financial reporting or auditing matters and any other matters relevant for their audit.

On an annual basis, PwC provides to the Audit and Compliance Committee the written disclosures required by Rule 3526, "Communications with Audit Committees Concerning Independence," of the Public Company Accounting Oversight Board (PCAOB), and the Audit and Compliance Committee and PwC discuss PwC's independence from Novartis and Novartis' management.

The Audit and Compliance Committee recommended to the Board of Directors, and the Board of Directors approved, inclusion of the audited financial statements in the Annual Report for the year ended December 31, 2012.

The Audit and Compliance Committee, on a regular basis, evaluates the performance of PwC and, once yearly, based on a performance evaluation, determines whether PwC should be proposed to the Annual General Meeting for election. Also, once yearly, the auditor in charge and the global relationship partner report to the Board of Directors on the activities of PwC during the current year and on the audit plan for the coming year and answer any questions or concerns Board members might have on the performance of PwC, or on the work PwC has conducted or is planning to conduct.

In order to assess the performance of PwC, the Audit and Compliance Committee requires a self-evaluation report from PwC, holds private meetings with the Chief Executive Officer, the Chief Financial Officer and with the Head of Internal Audit and, if necessary, obtains an independent external assessment. The Board of Directors also meets with the auditor in charge and the global relationship

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partner. Criteria applied for the performance assessment of PwC include technical and operational competence, independent and objective view, sufficient resources employed, focus on areas of significant risk to Novartis, willingness to probe and challenge, ability to provide effective, practical recommendations and open and effective communication and coordination with the Audit and Compliance Committee, the Internal Audit function and management.

#### **Pre-Approval of Audit and Non-Audit Services**

The Audit and Compliance Committee's pre-approval is required for all services provided by PwC. These services may include audit services, audit-related services, tax services and other services.

Pre-approval is detailed as to the particular services or categories of services, and is subject to a specific budget. PwC and management report, on a quarterly basis, to the Audit and Compliance Committee regarding the extent of services provided in accordance with this pre-approval and the fees for the services performed to date. The Audit and Compliance Committee may also pre-approve additional services on a case-by-case basis.

#### **Auditing and Additional Fees**

PwC charged the following fees for professional services rendered for the 12-month periods ended December 31, 2012 and December 31, 2011:

	2012	2011
	\$ thousands	\$ thousands
Audit Services	28,960	30,060
Audit-Related Services	2,300	2,480
Tax Services	500	1,550
Other Services	190	190
Total	31,950	34,280

Audit Services are defined as the standard audit work performed each year in order to issue opinions on the parent company and consolidated financial statements of the Group, to issue opinions relating to the effectiveness of the Group's internal controls over financial reporting, and to issue reports on local statutory financial statements. Also included are audit services that can only be provided by the Group auditor, such as auditing of non-recurring transactions and implementation of new accounting policies, audits of accounting infrastructure system controls, pre-issuance reviews of quarterly financial results, consents and comfort letters and any other audit services required for SEC or other regulatory filings.

Audit-Related Services include those other assurance services provided by the independent auditor but not restricted to those that can only be provided by the auditor signing the audit report. They comprise amounts for services such as acquisition due diligence and related audits, audits of pension and benefit plans, IT infrastructure control assessments, contractual audits of third-party arrangements, assurance services on corporate citizenship reporting and compliance with corporate integrity agreements, and consultation regarding new accounting pronouncements.

Tax Services represent tax compliance, tax returns, assistance with historical tax matters and other tax-related services.

Other Services include training in the finance area, advice for process improvements, benchmarking studies, assessment of certain non-financial processes and license fees for use of accounting and other reporting guidance databases.

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#### **FURTHER INFORMATION**

#### **The Group Structure of Novartis**

#### Novartis AG and Group Companies

Under Swiss company law, Novartis AG is organized as a corporation which has issued shares of common stock to investors. The registered office of Novartis AG is Lichtstrasse 35, CH-4056 Basel, Switzerland.

Business operations are conducted through Novartis Group companies. Novartis AG, a holding company, owns directly or indirectly all companies worldwide belonging to the Novartis Group. Except as described below, the shares of these companies are not publicly traded. The most important Novartis subsidiaries and associated companies are listed in Note 31 to the Group's consolidated financial statements.

#### **Divisions**

The businesses of Novartis are divided on a worldwide basis into six operating divisions, Pharmaceuticals, Alcon (eye care), Vaccines and Diagnostics, Sandoz (generics), Over-the-Counter and Animal Health, and Corporate activities.

### Majority Holdings in Publicly Traded Group Companies

Novartis AG holds 76% of Novartis India Limited, with its registered office in Mumbai, India, and listed on the Bombay Stock Exchange (ISIN INE234A01025, symbol: HCBA). The total market value of the 24% free float of Novartis India Limited was \$92.6 million at December 31, 2012, using the quoted market share price at the year end. Applying this share price to all the shares of the company the market capitalization of the whole company was \$392.5 million, and that of the shares owned by Novartis was \$299.9 million.

### Significant Minority Holdings in Publicly Traded Companies

Novartis AG holds

33.3% of the bearer shares of Roche Holding AG, with its registered office in Basel, Switzerland, and listed on the SIX Swiss Exchange (Valor No. 1203211, ISIN CH0012032113, symbol: RO). The market value of the Group's interest in Roche Holding AG, as of December 31, 2012, was \$10.9 billion. The total market value of Roche Holding AG was \$173.9 billion. Novartis does not exercise control over Roche Holding AG, which is independently governed, managed and operated.

24.9% of Idenix Pharmaceuticals, Inc., with its registered office in Delaware, USA, and listed on NASDAQ (Valor No. 1630029, ISIN US45166R2040, symbol: IDIX). The total market value of the 75.1% free float of Idenix Pharmaceuticals, Inc. was \$487.7 million at December 31, 2012, using the quoted market share price at the year end. Applying this share price to all the shares of the company the market capitalization of the whole company was \$649.3 million and that of the shares owned by Novartis was \$161.6 million. Novartis does not exercise control over Idenix Pharmaceuticals, Inc., which is independently governed, managed and operated.

#### **Information of our Stakeholders**

### Introduction

Novartis is committed to open and transparent communication with shareholders, financial analysts, customers, suppliers and other stakeholders. Novartis aims to disseminate material developments in its

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businesses in a broad and timely manner that complies with the rules of the SIX Swiss Exchange and the NYSE.

#### **Communications**

Novartis publishes an Annual Report each year that provides information on the Group's results and operations. In addition to the Annual Report, Novartis prepares an annual report on Form 20-F that is filed with the SEC. Novartis discloses quarterly financial results in accordance with IFRS and issues press releases from time to time regarding developments in its businesses.

Novartis furnishes press releases relating to financial results and material events to the SEC via Form 6-K. An archive containing Annual Reports, annual reports on Form 20-F, and quarterly results releases, as well as related materials such as slide presentations and conference call webcasts, is on the Novartis Investor Relations website (www.novartis.com/investors). The archive is available on the Novartis website: http://www.novartis.com/newsroom/media-releases/index.shtml

Information contained in reports and releases issued by Novartis is only correct and accurate at the time of release. Novartis does not update past releases to reflect subsequent events and advises against relying on them for current information.

#### **Investor Relations Program**

An Investor Relations team manages the Group's interaction with the international financial community. Several events are held each year to provide institutional investors and analysts various opportunities to learn more about Novartis.

Investor Relations is based at the Group's headquarters in Basel, Switzerland. A part of the team is located in New York to coordinate interaction with US investors. Information is available on the Novartis website: www.novartis.com/investors. Investors are also welcome to subscribe to a free e-mail service on this site.

#### **Website Information**

Topic	Information		
Share Capital	Articles of Incorporation of Novartis AG http://www.novartis.com/corporate-governance Novartis key share data http://www.novartis.com/key-share-data		
Shareholder Rights	Articles of Incorporation of Novartis AG http://www.novartis.com/corporate-governance Investor Relations information http://www.novartis.com/investors		
Board Regulations	Board Regulations http://www.novartis.com/corporate-governance		
<b>Executive Committee</b>	Executive Committee		

http://www.novartis.com/executive-committee

Novartis Code for Senior Financial Officers	Novartis Code of Ethical Conduct for CEO and Senior Financial Officers http://www.novartis.com/corporate-governance
Additional Information	Novartis Investor Relations http://www.novartis.com/investors
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### **6.D Employees**

The table below sets forth the breakdown of the total year-end number of our full time equivalent employees by main category of activity and geographic area for the past three years.

For the year ended December 31,	Research & Production & Marketing & General &					
2012 (full time equivalents)	Development	Supply	Sales Adm	inistration	Total	
USA	8,056	8,693	7,073	2,882	26,704	
Canada and Latin America	554	2,875	5,626	1,254	10,309	
Europe	10,994	22,405	19,421	6,608	59,428	
Asia/Africa/Australasia	3,569	5,613	19,855	2,246	31,283	
Total	23,173	39,586	51.975	12,990	127,724	

For the year ended December 31,	Research & Production & Marketing & General &					
2011 (full time equivalents)	Development	Supply	Sales Adn	ninistration	Total	
USA	8,269	7,785	8,930	2,258	27,242	
Canada and Latin America	537	2,713	5,541	1,146	9,937	
Europe	11,203	20,384	19,532	6,434	57,553	
Asia/Africa/Australasia	3,509	4,725	18,551	2,169	28,954	
Total	23,518	35,607	52,554	12,007	123,686	

For the year ended December 31,	Research & Production & Marketing & General &					
2010 (full time equivalents)	Development	Supply	Sales Adm	inistration	Total	
USA	7,995	7,186	9,942	2,464	27,587	
Canada and Latin America	555	2,660	5,435	1,064	9,714	
Europe	11,009	19,601	19,477	6,103	56,190	
Asia/Africa/Australasia	2,849	4,193	17,083	1,802	25,927	
Total	22,408	33,640	51,937	11,433	119,418	

Movements in full time equivalents	2012	2011
Associates as of January 1	123,686	119,418
Separations	(5,708)	(4,572)
Retirements	(934)	(751)
Resignations	(10,273)	(8,297)
External hirings	20,269	17,049
Impact of major business combinations	684	839
Total associates as of December 31	127,724	123,686

A significant number of our associates are represented by unions or works councils. We have not experienced any material work stoppages in recent years, and we consider our employee relations to be good.

# **6.E Share Ownership**

The aggregate amount of our shares owned by current non-executive Directors and the current members of our Executive Committee and Permanent Attendees (including persons closely linked to them) as of January 17, 2013 was 6,732,466 shares.

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The aggregate amount of Novartis share and ADS options, including other information regarding the options, held by current non-executive Directors and the current members of our Executive Committee and Permanent Attendees as of January 17, 2013 is set forth below:

Title of Outions	Amount of shares called for by the	Price <sup>(1)</sup>	Purchase Price	Euripetica Date	Total number of options
Title of Options	options	(CHF)	(if any)	Expiration Date February 3,	held
Novas14 Options	1	57.45	0	2014	9,559
Novas15 Options	1	57.45	0	February 3, 2015	34,127
Novas16 Options	1	71.30	0	February 5, 2016	101,446
Novas17 Options	1	72.85	0	February 3, 2017	898,530
Novas18 Options	1	64.05	0	January 10, 2018	273,708
Novas19 Options	1	53.65	0	January 18, 2019	643,140
Novas20 Options	1	55.85	0	January 17, 2020	982,610
Novas21 Options	1	54.70	0	January 19, 2021	141,396
110vas21 Options	1	54.70	U	January 19,	141,570
Novas22 Options	1	54.20	0	2022	0
Novas23 Options	1	61.70	0	January 17, 2023	0
<b>Total Novartis Share Options</b>					3,084,516
•					, ,
Novartis ADS Options Cycle VII	1	\$ 36.31	0	February 4, 2013	0
Novartis ADS Options Cycle VIII	1	\$ 46.09	0	February 3, 2014	0
Novartis ADS Options Cycle IX	1	\$ 47.84	0	February 3, 2015	151,659
				February 5,	
Novartis ADS Options Cycle X	1	\$ 54.70	0	2016 February 3,	124,876
Novartis ADS Options Cycle XI	1	\$ 58.38	0	2017	170,933
Novartis ADS Options Cycle XII	1	\$ 57.96	0	January 10, 2018	193,902
Novartis ADS Options Cycle XIII	1	\$ 46.42	0	January 18, 2019	0
Novartis ADS Options Cycle XIV	1	\$ 53.70	0	January 17, 2020	0
Novartis ADS Options Cycle XV	1	\$ 57.07	0	January 19, 2021	0
Novartis ADS Options Cycle XVI	1	\$ 58.33	0	January 19, 2022	50,764
Novartis ADS Options Cycle XVII	1	\$ 66.07	0	January 17, 2023	0
<b>Total Novartis ADS Options</b>					692,134

Exercise price indicated is per share, and denominated in Swiss francs except where indicated.

In addition, one Executive Committee member, Kevin Buehler, owns 605,877 other options, consisting of non tradable options and share settled appreciation rights, resulting from the conversion of Alcon equity into Novartis equity.

For more information on the Novartis shares and share options owned by individual members of our Executive Committee and by our current non-executive Directors, see " Item 6.B Compensation Ownership of Novartis Shares and Share Option by Executive Committee Members." and " Item 6.B Compensation Ownership of Novartis Shares and Share Option by Non-Executive Directors." For information on our equity-based compensation plans see " Item 6.B Compensation Compensation to Novartis Associates."

#### Item 7. Major Shareholders and Related Party Transactions

#### 7.A Major Shareholders

Novartis shares are widely held. As of December 31, 2012, Novartis had approximately 161,000 shareholders listed in its share register, representing 75% of issued shares. Based on the Novartis AG

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share register and excluding treasury shares, approximately 42% of the shares registered by name were held in Switzerland and 46% were held in the US. Approximately 12% of the shares registered in the share register were held by individual investors, while 88% were held by legal entities, nominees and fiduciaries.

Based on our share register, we believe that we are not directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons. There are no arrangements that may result in a change of control.

According to the share register, on December 31, 2012, no person or entity was registered as the owner of more than 5% of our shares. As of that date, excluding 4.09% of our share capital held by Novartis AG, together with Novartis affiliates, as treasury shares, the following registered shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 4.0%; and Emasan AG, with its registered office in Basel, Switzerland, holding 3.3%;

Nominees: JPMorgan Chase Bank, New York, NY (holding 11.4%); Nortrust Nominees, London, England (holding 3.3%); and The Bank of New York Mellon, New York, NY (holding 5.0%) through its nominees, Mellon Bank, Everett, MA (holding 3.3%) and The Bank of New York Mellon, Brussels, Belgium (1.7%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 11.7%).

According to a disclosure notification filed with Novartis AG, Norges Bank (Central Bank of Norway), Oslo, Norway, held 2.3% of the share capital of Novartis AG as of December 31, 2012.

According to disclosure notifications filed with Novartis AG and SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2012:

Capital Group Companies, Inc., Los Angeles, CA; and

BlackRock, Inc., New York, NY

As of December 31, 2012, no other shareholder was registered as owner of more than 2% of the registered share capital. Novartis has not entered into any agreement with any shareholder regarding the voting or holding of Novartis shares.

According to the share register, on December 31, 2011, no person or entity was registered as the owner of more than 5% of our shares. As of that date, excluding 5.76% of our share capital held by Novartis AG, together with Novartis affiliates, as treasury shares, the following shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 4.1% and Emasan AG, with its registered office in Basel, Switzerland, holding 3.2%;

Nominees: JPMorgan Chase Bank, New York, NY (holding 10.9%); Nortrust Nominees, London (holding 3.2%); Mellon Bank, Everett, MA (holding 3%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 11%).

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According to disclosure notifications filed with Novartis AG and SIX Swiss Exchange, Capital Group Companies, Inc., Los Angeles, CA held between 3% and 5% of the share capital of Novartis AG as of December 31, 2011.

As of December 31, 2011, no other shareholder was registered as owner of more than 2% of the registered share capital.

According to the share register, on December 31, 2010, no person or entity was registered as the owner of more than 5% of our shares. As of that date, excluding 6.3% of our share capital held by Novartis AG, together with Novartis affiliates, as treasury shares, the following shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 4.3% and Emasan AG, with its registered office in Basel, Switzerland, holding 3.3%;

Nominees: JPMorgan Chase Bank, New York, NY (holding 10.7%); Mellon Bank, Everett, MA (holding 2.9%); Nortrust Nominees, London, England (holding 2.8%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 9.6%).

According to disclosure notifications filed with Novartis AG and SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2010:

Capital Group Companies, Inc., Los Angeles, CA

BlackRock, Inc., New York, NY

#### 7.B Related Party Transactions

See "Item 18. Financial Statements note 27".

#### 7.C Interests of Experts and Counsel

Not applicable.

#### Item 8. Financial Information

### 8.A Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements."

### Dividend policy

Subject to the dividend policy described below, our Board of Directors expects to recommend the payment of a dividend in respect of each financial year. If approved by our shareholders at the relevant annual Shareholders' Meeting, the dividends will be payable shortly following such approval. Any shareholder who purchased our shares on or before the second trading day after the shareholders' meeting and holds the shares through that date shall be deemed to be entitled to receive the dividends approved at that meeting. Dividends are reflected in our financial statements in the year in which they are approved by our shareholders.

Our Board's stated policy is that, over the long term, the size of the dividend should be geared to growth in our after-tax earnings. In December 2007, our Board established a policy of paying dividends, subject to shareholder approval, of between 35% and 60% of our net income from continuing operations.

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In July 2011, in order to retain a good balance between attractive shareholder returns, investment in the business and a sound capital structure, our Board amended this policy by eliminating the 60% payout ceiling. However, all future dividends paid by us will depend upon our financial condition at the time, the results of our operations and other factors.

The Board will propose a dividend of CHF 2.30 per share to the shareholders for approval at the Annual General Meeting to be held on February 22, 2013. Because we pay dividends in Swiss francs, exchange rate fluctuations will affect the US dollar amounts received by holders of ADSs. For a summary of dividends we paid in the past five years, see "Item 3. Key Information 3.A Selected Financial Data Cash Dividends per Share." See also "Item 3. Key Information 3.D Risk Factors The price of our ADSs and the US dollar value of any dividends may be negatively affected by fluctuations in the US dollar/Swiss franc exchange rate."

#### Disclosure pursuant to Section 219 of the Iran Threat Reduction & Syria Human Rights Act (ITRA)

At Novartis, it is our mission to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life of all people, regardless of where they live. As part of that mission, and in connection with the sale of medicines and other healthcare products in Iran, a non-US affiliate within our Pharmaceuticals Division has entered into a non-binding Memorandum of Understanding (MoU) with the Ministry of Health and Medical Education of the Islamic Republic of Iran, dated October 18, 2010. Pursuant to the MoU, the Iranian Ministry of Health acknowledges certain benefits that may apply to sales of certain Novartis Pharmaceuticals medicines by third-party distributors in Iran. These include fast-track registration, market exclusivity, end-user subsidies and exemptions from customs tariffs. Novartis receives no payments from the Iranian Ministry of Health under the MoU and the MoU creates no obligations on the part of either Novartis or the Iranian Ministry of Health.

To our knowledge, none of our sales of products in Iran during 2012 are required to be disclosed pursuant to ITRA Section 219, with the following possible exception: During 2012, non-US affiliates within our Vaccines and Diagnostics Division sold influenza vaccines and rabies vaccines to Medical Equipment and Pharmaceutical Holding Co. of Iran, which we understand is an affiliate of the Iranian Ministry of Health. Our gross sales of these influenza and rabies vaccines during 2012 were EUR 185,000 and EUR 1,362,500 respectively, and our net profits (gross sales minus cost of goods sold and commissions) from such sales were EUR 43,300 and EUR 397,501, respectively. We expect to continue to make sales of vaccines to this customer during 2013.

#### 8.B Significant Changes

None.

# Item 9. The Offer and Listing

### 9.A Listing Details

Our shares are listed in Switzerland on the SIX Swiss Exchange (SIX).

American Depositary Shares, each representing one share, have been available in the US through an American Depositary Receipts (ADR) program since December 1996. This program was established pursuant to a Deposit Agreement which we entered into with JPMorgan Chase Bank N.A. as Depositary (Deposit Agreement). Our ADSs have been listed on the NYSE since May 2000, and are traded under the symbol "NVS."

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The table below sets forth, for the periods indicated, the high and low closing sales prices for our shares traded in Switzerland and for ADSs traded in US. The data below regarding our shares reflects price and volume information for trades completed by members of the SIX during the day as well as for inter-dealer trades completed off the SIX and certain inter-dealer trades completed during trading on the previous business day.

The following share data was taken from SIX; the ADS data was taken from Bloomberg:

	Shares		ADSs	
	High	Low	High	Low
	CHF per	share	\$ per ADS	
Annual information for the past five years				
2008	66.25	45.62	61.06	43.85
2009	56.90	39.64	56.16	33.96
2010	60.25	50.55	59.77	43.78
2011	55.80	39.99	64.52	51.65
2012	59.00	48.80	63.96	51.48
Quarterly information for the past two years				
2012				
First Quarter	54.70	49.00	58.33	53.31
Second Quarter	52.90	48.80	56.38	51.48
Third Quarter	58.75	53.35	61.51	55.23
Fourth Quarter	59.00	55.45	63.96	58.97
2011				
First Quarter	55.80	48.10	59.24	52.75
Second Quarter	55.00	48.62	64.52	54.23
Third Quarter	52.15	39.99	62.82	53.73
Fourth Quarter	53.70	47.80	58.86	51.65
Monthly information for most recent six months				
August 2012	58.75	56.25	60.52	58.28
September 2012	57.65	55.60	61.51	58.53
October 2012	59.00	56.05	63.72	60.46
November 2012	57.65	55.45	62.05	58.97
December 2012	58.85	57.45	63.96	62.32
January 2013 (through January 17)	61.70	58.70	66.07	63.70
	1.1 770	1 11 111 0		

Fluctuations in the exchange rate between the Swiss franc and the US dollar will affect any comparisons of Swiss share prices and US ADS prices.

The average daily volumes traded on the SIX (ON/OFF exchange) for the years 2012, 2011 and 2010 were 4,637,552, 7,036,042, and 6,216,952, respectively. These numbers are based on total annual turnover statistics supplied by the SIX via the Swiss Market Feed, which supplies such data to subscribers and to other information providers. The average daily volumes traded in the US for the years 2012, 2011 and 2010 were 2,187,889, 3,492,488, and 3,515,307, respectively.

The Depositary has informed us that as of January 17, 2013, there were 316,268,983 ADSs outstanding, each representing one Novartis share (approximately 12% of total Novartis shares issued). On January 17, 2013, the closing sales price per share on the SIX was CHF 61.70 and \$66.07 per ADS on the NYSE.

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9.B Plan of Distribution
Not applicable.
9.C Market
See "9.A Listing Details."
9.D Selling Shareholders
Not applicable.
9.E Dilution
Not applicable.
9.F Expenses of the Issue
Not applicable.
Item 10. Additional Information
10.A Share capital
Not applicable.
10 P Marraman dum and Anticles of Association
10.B Memorandum and Articles of Association
The following is a summary of certain provisions of our Articles of Incorporation (Articles), our Regulations of the Board of Directors (Board Regulations) and of Swiss law, particularly, the Swiss Code of Obligations (Swiss Code). This is not a summary of all the significant provisions of the Articles, the Board Regulations or of Swiss law. This summary is qualified in its entirety by reference to the Articles and the Board Regulations, which are an exhibit to this Form 20-F, and to Swiss law.
10.B.1 Company Purpose
Novartis AG is registered in the commercial register of the Canton of Basel-Stadt, Switzerland, under number CH-270.3.002.061-2. Our business purpose, as stated in Article 2 of the Articles, is to hold interests in enterprises in the area of healthcare or nutrition. We may also hold

# 10.B.2 Directors

value.

(a) According to our Board Regulations, our Directors may not participate in deliberations or resolutions on matters which affect, or reasonably might affect, the Director's interests, or the interests of a person close to the Director. In addition, the Swiss Code sets forth that if, in

interests in enterprises in the areas of biology, chemistry, physics, information technology or related areas. We may acquire, mortgage, liquidate or sell real estate and intellectual property rights in Switzerland or abroad. In pursuing our business purpose, we strive to create sustainable

connection with the conclusion of a contract, the Company is represented by the person with whom it is concluding the contract, such contract shall be in writing. Furthermore, the Swiss Code does require directors and members of senior management to safeguard the interests of the corporation and, in this connection, imposes a duty of care and a duty of loyalty on such persons. This rule is generally interpreted to mean that directors and members of senior management are disqualified from participating in decisions which affect them personally.

(b) As with any Board resolution, Directors may not vote on their own compensation unless at least a majority of the Directors are present.

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- (c) The Articles and the Board Regulations contain no specific provision permitting or prohibiting Directors from borrowing from us. The Board of Directors may take decisions on all matters which by law or the Articles are not allocated to the General Meeting of Shareholders.
- (d) Directors must retire after the end of their seventieth year of age, but the retirement does not become effective until the date of the next Ordinary General Meeting of Shareholders. The General Meeting of Shareholders may, under special circumstances, grant an exemption from this rule and may elect a Director for further terms of office of no more than three years at a time.
  - (e) Under the Articles, each of our Directors must also be a shareholder. Ownership of one share is sufficient to satisfy this requirement.

#### 10.B.3 Shareholder Rights

Because we have only one class of registered shares, the following information applies to all shareholders.

(a) The Swiss Code requires that at least 5% of our annual profit be retained as general reserves, so long as these reserves amount to less than 20% of our registered share capital. The law and the Articles permit us to accrue additional reserves.

Under the Swiss Code, we may only pay dividends out of the balance sheet profit or out of reserves created for this purpose. In either event, under the Swiss Code, while the Board of Directors may propose that a dividend be paid, we may only pay dividends upon shareholders' approval at a General Meeting of Shareholders. Our auditors must confirm that the dividend proposal of our Board of Directors conforms with the Swiss Code and the Articles. Our Board of Directors intends to propose a dividend once each year. See "Item 3. Key Information 3.A. Selected Financial Data Cash Dividends per Share."

Dividends are usually due and payable shortly after the shareholders have passed a resolution approving the payment. Dividends which have not been claimed within five years after the due date revert to us, and are allocated to our general reserves. For information about deduction of the withholding tax from dividend payments, see "Item 10. Additional Information 10.E Taxation."

(b) Each share is entitled to one vote at a General Meeting of Shareholders. Voting rights may only be exercised for shares registered with the right to vote on the Record Date. In order to do so, the shareholder must file a share registration form with us, setting forth the shareholder's name, address and citizenship (or, in the case of a legal entity, its registered office). If the shareholder has not timely filed the form, then the shareholder may not vote at, or participate in, General Meetings of Shareholders.

To vote its shares, the shareholder must also explicitly declare that it has acquired the shares in its own name and for its own account. If the shareholder refuses to make such a declaration, the shares may not be voted unless the Board of Directors recognizes such shareholder as nominee. The Board of Directors may grant such nominees the right to vote up to 0.5% of the registered share capital as set forth in the commercial register.

Except as described below, no shareholder may be registered with the right to vote shares composing more than 2% of our registered share capital as set forth in the commercial register. If a shareholder holds more than 2% of Novartis' shares, that shareholder will be entitled to register the excess shares, but not to cast votes based upon them (registration without the right to vote).

For purposes of the 2% rule for shareholders and the 0.5% rule for nominees, groups of companies and groups of shareholders acting in concert are considered to be one shareholder. The Board of Directors may, upon request, grant exemptions from both the 2% rule for shareholders and the 0.5% rule for nominees. The Board of Directors may delegate this power. Finally, the shareholders may cancel the registration restrictions upon a resolution carrying a two-thirds majority of the vote at a General Meeting of Shareholders.

After hearing the registered shareholder or nominee, the Board of Directors may cancel, with retroactive effect as of the date of registration, the registration of the shareholders if the registration was effected based on false information.

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Shareholders' resolutions generally require the approval of a majority of the votes present at a General Meeting of Shareholders. As a result, abstentions have the effect of votes against the resolution. Shareholder resolutions requiring a vote by such "absolute majority" include (1) amendments to the Articles; (2) elections of directors and statutory auditors; (3) approval of the annual report and the annual accounts; (4) setting the annual dividend; (5) decisions to discharge directors and management from liability for matters disclosed to the General Meeting of Shareholders; and (6) the ordering of an independent investigation into specific matters proposed to the General Meeting of Shareholders.

According to the Articles and Swiss law, the following types of shareholders' resolutions require the approval of a "supermajority" of at least two-thirds of the votes present at a General Meeting of Shareholders: (1) an alteration of our corporate purpose; (2) the creation of shares with increased voting powers; (3) an implementation of restrictions on the transfer of registered shares and the removal of such restrictions; (4) an authorized or conditional increase of the share capital; (5) an increase of the share capital by conversion of equity, by contribution in kind, or for the purpose of an acquisition of property or the grant of special rights; (6) a restriction or an elimination of shareholders' preemptive rights; (7) a change of our domicile; (8) our dissolution; or (9) any amendment to the Articles which would create or eliminate a supermajority requirement.

The Directors' terms of office shall be coordinated so that in each year approximately one-third of all the Directors are subject to re-election or election. Cumulative voting of shares is not permitted under Swiss law.

At General Meetings of Shareholders, shareholders can be represented by proxy. However, a proxy must either be the shareholder's legal representative, another shareholder with the right to vote, a proxy appointed by us, an independent representative nominated by us, or a depositary. Votes are taken either by a show of hands or by electronic voting, unless the General Meeting of Shareholders resolves to have a ballot or where a ballot is ordered by the chairman of the meeting.

A holder of a Novartis American Depositary Receipt (ADR) has a paper receipt issued by our depositary JPMorgan Chase Bank, New York, and not by us. The ADR is vested with rights defined and enumerated in the Deposit Agreement (such as the rights to vote, to receive a dividend and to receive a share of Novartis in exchange for a certain number of ADRs). The enumeration of rights, including any limitations on those rights, is final. There are no other rights given to the ADR holders. Only the ADR depositary, holding our shares underlying the ADRs, is registered as shareholder in our share register. An ADR is not a Novartis share and an ADR holder is not a Novartis shareholder.

The Deposit Agreement between our depositary, the ADR holder and us has granted the right to vote to the ADR holders. ADR holders may not attend Novartis General Meetings in person. ADR holders exercise their voting rights by instructing JPMorgan Chase Bank, our depositary, to exercise the voting rights attached to the registered shares underlying the ADRs. Each ADR represents one Novartis share. JPMorgan Chase Bank exercises the voting rights for registered shares underlying ADRs for which no voting instructions have been given by providing a discretionary proxy to the independent proxy appointed by Novartis pursuant to paragraph 13 of the Deposit Agreement governing ADRs. The same voting restrictions apply to ADR holders as to those holding Novartis shares (i.e. the right to vote up to 2% of the Novartis registered share capital unless otherwise granted an exemption by the Board and disclosure requirement for nominees).

- (c) Shareholders have the right to allocate the profit shown on our balance sheet by vote taken at the General Meeting of Shareholders, subject to the legal requirements described in "Item 10.B.3(a) Shareholder Rights".
- (d) Under the Swiss Code, any surplus arising out of a liquidation of our company (*i.e.*, after the settlement of all claims of all creditors) would be distributed to the shareholders in proportion to the paid-in nominal value of their shares.
- (e) The Swiss Code limits a corporation's ability to hold or repurchase its own shares. We and our subsidiaries may only repurchase shares if we have freely disposable equity, in the amount necessary for

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this purpose, available. The aggregate nominal value of all Novartis shares held by us and our subsidiaries may not exceed 10% of our registered share capital. However, it is accepted that a corporation may repurchase its own shares beyond the statutory limit of 10%, if the repurchased shares are clearly dedicated for cancellation and if the shareholders passed a respective resolution at a General Meeting of Shareholders. In addition, we are required to create a special reserve on our balance sheet in the amount of the purchase price of the acquired shares. Repurchased shares held by us or our subsidiaries do not carry any rights to vote at a General Meeting of Shareholders, but are entitled to the economic benefits generally connected with the shares. It should be noted that the definition of what constitutes subsidiaries, and therefore, treasury shares, for purposes of the above described reserves requirement and voting restrictions differs from the definition included in the consolidated financial statements. The definition in the consolidated financial statements requires consolidation for financial reporting purposes of special purpose entities, irrespective of their legal structure, in instances where we have the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

Under the Swiss Code, we may not cancel treasury shares without the approval of a capital reduction by our shareholders.

- (f) Not applicable.
- (g) Since all of our issued and outstanding shares have been fully paid in, we can make no further capital calls on our shareholders.
- (h) See Items "10.B.3(b) Shareholder Rights" and "10.B.7 Change in Control".

#### 10.B.4 Changes To Shareholder Rights

Under the Swiss Code, we may not issue new shares without the prior approval of a capital increase by our shareholders. If a capital increase is approved, then our shareholders would generally have certain preemptive rights to obtain newly issued shares in an amount proportional to the nominal value of the shares they already hold. These preemptive rights could be modified in certain limited circumstances with the approval of a resolution adopted at a General Meeting of Shareholders by a supermajority of votes. In addition, we may not create shares with increased voting powers or place restrictions on the transfer of registered shares without the approval of a resolution adopted at a General Meeting of Shareholders by a supermajority of votes. In addition, see Item 10.B.3(b) with regard to the Board of Directors' ability to cancel the registration of shares under limited circumstances.

# 10.B.5 Shareholder Meetings

Under the Swiss Code and the Articles, we must hold an annual ordinary General Meeting of Shareholders within six months after the end of our financial year. General Meetings of Shareholders may be convened by the Board of Directors or, if necessary, by the statutory auditors. The Board of Directors is further required to convene an extraordinary General Meeting of Shareholders if so resolved by a General Meeting of Shareholders, or if so requested by shareholders holding an aggregate of at least 10% of the registered shares, specifying the items for the agenda and their proposals. Shareholders holding shares with a nominal value of at least CHF 1,000,000 (*i.e.*, 2,000,000 Novartis shares) have the right to request that a specific proposal be put on the agenda and voted upon at the next General Meeting of Shareholders. A General Meeting of Shareholders is convened by publishing a notice in the official Swiss Commercial Gazette (*Schweizerisches Handelsamtsblatt*) at least 20 days prior to such meeting. Shareholders may also be informed by mail. There is no provision in the Swiss Code or our Articles requiring a quorum for the holding of a General Meeting of Shareholders. In addition see "Item 10.B.3(b) Shareholder Rights" regarding conditions for exercising a shareholder's right to vote at a General Meeting of Shareholders.

#### 10.B.6 Limitations

There are no limitations under the Swiss Code or our Articles on the right of non-Swiss residents or nationals to own or vote shares other than the restrictions applicable to all shareholders. But see "Item 10.B.3(b) Shareholder Rights" regarding conditions for exercising an ADR holder's right to vote at a shareholder meeting.

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#### 10.B.7 Change in Control

The Articles and the Board Regulations contain no provision that would have an effect of delaying, deferring or preventing a change in control of Novartis and that would operate only with respect to a merger, acquisition or corporate restructuring involving us or any of our subsidiaries.

According to the Swiss Merger Act, shareholders may pass a resolution to merge with another corporation at any time. Such a resolution would require the consent of at least two-thirds of all votes present at the necessary General Meeting of Shareholders.

Under the Swiss Stock Exchange Act, shareholders and groups of shareholders acting in concert who acquire more than 33<sup>1</sup>/<sub>3</sub>% of our shares would be under an obligation to make an offer to acquire all remaining Novartis shares.

#### 10.B.8 Disclosure of Shareholdings

Under the Swiss Stock Exchange Act, holders of our voting shares acting alone or acting in concert with others are required to notify us and the SIX Swiss Exchange of the level of their holdings whenever such holdings reach or exceed, or in some cases, fall short of, certain thresholds 3%, 5%, 10%, 15%, 20%, 25%, 393%, 50% and 66<sup>2</sup>/<sub>3</sub>% of our registered share capital. Following receipt of such notification we are required to inform the public by publishing the information via the electronic publication platform operated by the competent Disclosure Office.

An additional disclosure obligation exists under the Swiss Code which requires us to disclose, once a year in the notes to the financial statements published in our annual report, the identity of all of our shareholders (or related groups of shareholders) who have been granted exemption entitling them to vote more than 2% of our registered share capital, as described in "Item 10.B.3(b) Shareholder Rights".

### 10.B.9 Differences in the Law

See the references to Swiss law throughout this "Item 10.B Memorandum and Articles of Association".

### 10.B.10 Changes in Capital

The requirements of the Articles regarding changes in capital are not more stringent than the requirements of Swiss law.

#### 10.C Material contracts

In April 2008, we entered into an agreement with Nestlé S.A. of Switzerland under which we obtained the right to acquire majority ownership in Alcon Inc. (NYSE: ACL) in two steps. The first step was completed on July 7, 2008, when we acquired an initial 25% stake (74 million shares) from Nestlé for \$10.4 billion in cash. This investment reflects a price of \$140.68 per share (the initial transaction price of \$143.18, later reduced to account for the dividend paid by Alcon in May 2008). In the second step, we had the right to acquire Nestlé's remaining 52% majority stake in Alcon between January 1, 2010 and July 31, 2011 for a fixed price of \$181.00 per share, or approximately \$28 billion. Novartis completed the second step, acquiring Nestlé's 52% stake, on August 25, 2010, for approximately \$28.3 billion, or \$180 per share.

On December 14, 2010, we entered into a definitive agreement with Alcon to merge Alcon into Novartis. During the period from January to April 8, 2011, we acquired 4.8% of the shares in Alcon for \$2.4 billion. On April 8, 2011, the Novartis Extraordinary General Meeting approved the merger with Alcon, Inc. creating the global leader in eye care. As a result, the new Alcon Division became the fifth

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growth platform in our strategically diversified healthcare portfolio. The Extraordinary General Meeting also authorized the issuance of 108 million new shares.

Under the terms of the December 14, 2010 agreement, Alcon shareholders received 2.9228 Novartis shares (which amount included a dividend adjustment) and \$8.20 in cash for each share of Alcon, resulting in a total consideration of \$168.00 per share. The completion of the acquisition of the outstanding 18.6% non-controlling interest in Alcon on April 8 and the subsequent merger resulted in the issuance of Novartis shares with a fair value of \$9.2 billion, and a contingent value payment of \$0.5 billion.

#### 10.D Exchange controls

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to Novartis, the export or import of capital, including any foreign exchange controls, or that affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold Novartis' shares.

#### 10.E Taxation

The taxation discussion set forth below is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects relevant to the ownership or disposition of our shares or ADSs. The statements of US and Swiss tax laws set forth below are based on the laws and regulations in force as of the date of this 20-F, including the current Convention Between the United States and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, entered into force on December 19, 1997 (the "Treaty"), and the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations, rulings, judicial decisions and administrative pronouncements, and may be subject to any changes in US and Swiss law, and in any double taxation convention or treaty between the United States and Switzerland occurring after that date, which changes may have retroactive effect.

#### **Swiss Taxation**

#### Swiss Residents

Withholding Tax on Dividends and Distributions. Dividends which we pay and similar cash or in-kind distributions which we may make to a holder of shares or ADSs (including distributions of liquidation proceeds in excess of the nominal value, stock dividends and, under certain circumstances, proceeds from repurchases of shares by us in excess of the nominal value) are generally subject to a Swiss federal withholding tax (the "Withholding Tax") at a current rate of 35%. Under certain circumstances distributions out of capital contribution reserves made by shareholders after December 31, 1996 are exempt from Withholding Tax. We are required to withhold this Withholding Tax from the gross distribution and to pay the Withholding Tax to the Swiss Federal Tax Administration. The Withholding Tax is refundable in full to Swiss residents who are the beneficial owners of the taxable distribution at the time it is resolved and duly report the gross distribution received on their personal tax return or in their financial statements for tax purposes, as the case may be.

Income Tax on Dividends. A Swiss resident who receives dividends and similar distributions (including stock dividends and liquidation surplus) on shares or ADSs is required to include such amounts in the shareholder's personal income tax return. However, distributions out of qualified capital contribution reserves are not subject to income tax. A corporate shareholder may claim substantial relief from taxation of dividends and similar distributions received if the shares held represent a fair market value of at least CHF 1 million.

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Capital Gains Tax upon Disposal of Shares. Under current Swiss tax law, the gain realized on shares held by a Swiss resident who holds shares or ADSs as part of his private property is generally not subject to any federal, cantonal or municipal income taxation on gains realized on the sale or other disposal of shares or ADSs. However, gains realized upon a repurchase of shares by us may be characterized as taxable dividend income if certain conditions are met. Book gains realized on shares or ADSs held by a Swiss corporate entity or by a Swiss resident individual as part of the shareholder's business property are, in general, included in the taxable income of such person. However, the Federal Law on the Direct Federal Tax of December 14, 1990 and several cantonal laws on direct cantonal taxes provide for exceptions for Swiss corporate entities holding more than 10% of our voting stock for more than one year.

#### Residents of Other Countries

Recipients of dividends and similar distributions on the shares who are neither residents of Switzerland for tax purposes nor holding shares as part of a business conducted through a permanent establishment situated in Switzerland ("Non-resident Holders") are not subject to Swiss income taxes in respect of such distributions. Moreover, gains realized by such recipients upon the disposal of shares are not subject to Swiss income taxes.

Non-resident Holders of shares are, however, subject to the Withholding Tax on dividends and similar distributions mentioned above and under certain circumstances to the Stamp Duty described below. Such Non-resident Holders may be entitled to a partial refund of the Withholding Tax if the country in which they reside has entered into a bilateral treaty for the avoidance of double taxation with Switzerland. Non-resident Holders should be aware that the procedures for claiming treaty refunds (and the time frame required for obtaining a refund) may differ from country to country. Non-resident Holders should consult their own tax advisors regarding receipt, ownership, purchase, sale or other dispositions of shares or ADSs and the procedures for claiming a refund of the Withholding Tax.

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Estonia

Finland

As of January 1, 2013, Switzerland has entered into bilateral treaties for the avoidance of double taxation with respect to income taxes with the following countries, whereby a part of the above-mentioned Withholding Tax may be refunded (subject to the limitations set forth in such treaties):

Singapore Albania France Latvia Lithuania Slovak Republic Algeria Germany Armenia Georgia Luxembourg Slovenia Australia Ghana Macedonia South Africa Austria Greece Malaysia Spain Azerbaijan Hong Kong Malta Sri Lanka Bahrain Hungary Mexico Sweden Bangladesh Iceland Moldova Taiwan Tajikistan Belarus India Mongolia Indonesia Belgium Montenegro Thailand Bulgaria Iran Morocco Trinidad and Tobago Canada Netherlands Tunisia Israel Chile Turkey Italy New Zealand China **Ivory Coast** Norway Ukraine Colombia Republic of Ireland Pakistan United Arab Emirates Croatia Jamaica Philippines United Kingdom Czech Republic Japan Poland United States of America Portugal Denmark Kazakhstan Uruguay Ecuador Republic of Korea **Ouatar** Uzbekistan Egypt (South Korea) Romania Venezuela

Kuwait

Kyrgyzstan

Tax treaty negotiations are under way, or have been concluded, with Argentina (treaty not yet in force but provisionally applicable as from January 1, 2001), Brazil, Costa Rica, Libya, North Korea, Oman, Peru, Saudi Arabia, Senegal, Syria, Turkmenistan, and Zimbabwe.

Vietnam

Russia

Serbia

A Non-resident Holder of shares or ADSs will not be liable for any Swiss taxes other than the Withholding Tax described above and, if the transfer occurs through or with a Swiss bank or other Swiss securities dealer, the Stamp Duty described below. If, however, the shares or ADSs of Non-resident Holders can be attributed to a permanent establishment or a fixed place of business maintained by such person within Switzerland during the relevant tax year, the shares or ADSs may be subject to Swiss income taxes in respect of income and gains realized on the shares or ADSs and such person may qualify for a full refund of the Withholding Tax based on Swiss tax law.

Residents of the United States. A Non-resident Holder who is a resident of the United States for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 15% of the dividend, provided that such holder (i) qualifies for benefits under the Treaty, (ii) holds, directly and indirectly, less than 10% of our voting stock, and (iii) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares or ADSs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 15% Treaty rate. A Non-resident Holder who is a resident of the United States for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 5% of the dividend, provided that such holder (i) is a company, (ii) qualifies for benefits under the Treaty, (iii) holds directly at least 10% of our voting stock, and (iv) does not conduct business through a permanent establishment or fixed place of business in Switzerland to which the shares or ADSs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 5% Treaty rate. Claims for refunds must be filed on Swiss Tax Form 82 (82C for corporations; 82I for individuals; 82E for other entities), which may be obtained from any Swiss

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Consulate General in the United States or from the Federal Tax Administration of Switzerland at the address below, together with an instruction form. Four copies of the form must be duly completed, signed before a notary public of the United States, and sent to the Federal Tax Administration of Switzerland, Eigerstrasse 65, CH-3003 Berne, Switzerland. The form must be accompanied by suitable evidence of deduction of Swiss tax withheld at source, such as certificates of deduction, signed bank vouchers or credit slips. The form may be filed on or after July 1 or January 1 following the date the dividend was payable, but no later than December 31 of the third year following the calendar year in which the dividend became payable. For US resident holders of ADSs, JPMorgan Chase Bank, N.A., as Depositary, will comply with these Swiss procedures on behalf of the holders, and will remit the net amount to the holders.

Stamp Duty upon Transfer of Securities. The sale of shares, whether by Swiss residents or Non-resident Holders, may be subject to federal securities transfer Stamp Duty of 0.15%, calculated on the sale proceeds, if the sale occurs through or with a Swiss bank or other Swiss securities dealer, as defined in the Swiss Federal Stamp Duty Act. The Stamp Duty has to be paid by the securities dealer and may be charged to the parties in a taxable transaction who are not securities dealers. Stamp Duty may also be due if a sale of shares occurs with or through a non-Swiss bank or securities dealer, provided (i) such bank or dealer is a member of the SIX, and (ii) the sale takes place on the SIX. In addition to this Stamp Duty, the sale of shares by or through a member of the SIX may be subject to a minor stock exchange levy.

#### **United States Federal Income Taxation**

The following is a general discussion of the material US federal income tax consequences of the ownership and disposition of our shares or ADSs that may be relevant to you if you are a US Holder (as defined below). Because this discussion does not consider any specific circumstances of any particular holder of our shares or ADSs, persons who are subject to US taxation are strongly urged to consult their own tax advisers as to the overall US federal, state and local tax consequences, as well as to the overall Swiss and other foreign tax consequences, of the ownership and disposition of our shares or ADSs. In particular, additional or different rules may apply to US expatriates, banks and other financial institutions, regulated investment companies, traders in securities who elect to apply a mark-to-market method of accounting, dealers in securities or currencies, tax-exempt entities, insurance companies, broker-dealers, investors liable for alternative minimum tax, investors that hold shares or ADSs as part of a straddle, hedging or conversion transaction, holders whose functional currency is not the US dollar, partnerships or other pass through entities, persons who acquired our shares pursuant to the exercise of employee stock options or otherwise as compensation and persons who hold directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares. This discussion generally applies only to US Holders who hold the shares or ADSs as a capital asset (generally, for investment purposes), and whose functional currency is the US dollar. Investors are urged to consult their own tax advisors concerning whether they are eligible for benefits under the Treaty.

For purposes of this discussion, a "US Holder" is a beneficial owner of our shares or ADSs who is (i) an individual who is a citizen or resident of the United States for US federal income tax purposes, (ii) a corporation (or other entity taxable as a corporation for US federal income tax purposes) created or organized in or under the laws of the US or a state thereof or the District of Columbia, (iii) an estate the income of which is subject to US federal income taxation regardless of its source, or (iv) a trust (i) subject to the primary supervision of a US court and the control of one or more US persons or (ii) that has a valid election in place to be treated as a US person. If a partnership (or other entity treated as a partnership for US federal income tax purposes) holds shares or ADSs, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. Partners in a partnership that holds shares or ADSs are urged to consult their own tax advisor regarding the specific tax consequences of the owning and disposing of such shares or ADSs by the partnership.

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For US federal income tax purposes, a US Holder of ADSs generally will be treated as the beneficial owner of our shares represented by the ADSs. However, see the discussion below under " Dividends" regarding certain statements made by the US Treasury concerning depositary arrangements.

This discussion assumes that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms.

Dividends. US Holders will be required to include in gross income, as an item of ordinary income, the full amount (including the amount of any Withholding Tax) of a dividend paid with respect to our shares or ADSs at the time that such dividend is received by the US Holder, in the case of shares, or by the Depository, in the case of ADSs. For this purpose, a "dividend" will include any distribution paid by us with respect to our shares or ADSs (other than certain pro rata distributions of our capital stock) paid out of our current or accumulated earnings and profits, as determined under US federal income tax principles. To the extent the amount of a distribution by us exceeds our current and accumulated earnings and profits, such excess will first be treated as a tax-free return of capital to the extent of a US Holder's tax basis in the shares or ADSs (with a corresponding reduction in such tax basis), and thereafter will be treated as capital gain, which will be long-term capital gain if the US Holder held our shares or ADSs for more than one year. Under the Code, dividend payments by us on the shares or ADSs are not eligible for the dividends received deduction generally allowed to corporate shareholders.

Dividend income in respect of our shares or ADSs will constitute income from sources outside the United States for US foreign tax credit purposes. Subject to the limitations and conditions provided in the Code, US Holders generally may claim as a credit against their US federal income tax liability, any Withholding Tax withheld from a dividend. The rules governing the foreign tax credit are complex. Each US Holder is urged to consult its own tax advisor concerning whether, and to what extent, a foreign tax credit will be available with respect to dividends received from us. Alternatively, a US Holder may claim the Withholding Tax as a deduction for the taxable year within which the Withholding Tax is paid or accrued, provided a deduction is claimed for all of the foreign income taxes the US Holder pays or accrues in the particular year. A deduction does not reduce US tax on a dollar-for-dollar basis like a tax credit. The deduction, however, is not subject to the limitations applicable to foreign tax credits.

The US Treasury has expressed concern that parties to whom ADSs are released may be taking actions inconsistent with the claiming of foreign tax credits for US Holders of ADSs. Accordingly, the summary above of the creditability of the Withholding Tax could be affected by future actions that may be taken by the US Treasury.

In general, a US Holder will be required to determine the amount of any dividend paid in Swiss francs, including the amount of any Withholding Tax imposed thereon, by translating the Swiss francs into US dollars at the spot rate on the date the dividend is actually or constructively received by a US Holder, in the case of shares, or by the Depositary, in the case of ADSs, regardless of whether the Swiss francs are in fact converted into US dollars. If a US Holder converts the Swiss francs so received into US dollars on the date of receipt, the US Holder generally should not recognize foreign currency gain or loss on such conversion. If a US Holder does not convert the Swiss francs so received into US dollars on the date of receipt, the US Holder will have a tax basis in the Swiss francs equal to the US dollar value on such date. Any foreign currency gain or loss that a US Holder recognizes on a subsequent conversion or other disposition of the Swiss francs generally will be treated as US source ordinary income or loss.

For a non-corporate US Holder, the US dollar amount of any dividends paid to it prior to January 1, 2013 that constitute qualified dividend income generally will be taxable at a maximum rate of 15%. For tax years beginning after 2012, the top rate is 20% for taxpayers with incomes exceeding \$400,000 (\$450,000 for joint filing taxpayers) provided that the US Holder meets certain holding period and other requirements. In addition, the dividends could be subject to a 3.8% net investment income tax. This tax is applied against the lesser of the US Holder's net investment income or modified adjusted gross income over \$200,000 (\$250,000 for joint filing taxpayers). We currently believe that dividends paid with respect to

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our shares and ADSs will constitute qualified dividend income for US federal income tax purposes. However, the US Treasury and the US Internal Revenue Service ("IRS") have announced their intention to promulgate rules pursuant to which US Holders of shares and ADSs, among others, will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. US Holders of shares or ADSs are urged to consult their own tax advisors regarding the availability to them of the reduced dividend rate in light of their own particular situation and the computations of their foreign tax credit limitation with respect to any qualified dividends paid to them, as applicable.

Sale or Other Taxable Disposition. Upon a sale or other taxable disposition of shares or ADSs, US Holders generally will recognize capital gain or loss in an amount equal to the difference between the US dollar value of the amount realized on the disposition and the US Holder's tax basis (determined in US dollars) in the shares or ADSs. This capital gain or loss generally will be US source gain or loss and will be treated as long-term capital gain or loss if the holding period in the shares or ADSs exceeds one year. In the case of certain US Holders (including individuals), any long term capital gain generally will be subject to US federal income tax at preferential rates, which rates are subject to a maximum of 20% for taxpayers with incomes exceeding \$400,000 (\$450,000 for joint filing taxpayers) for gains recognized after January 1, 2013. In addition, the gains could be subject to a 3.8% investment income tax. This tax is applied against the lesser of the US Holder's net investment income or modified adjusted gross income over \$200,000 (\$250,000 for joint filing taxpayers). The deductibility of capital losses is subject to significant limitations under the Code. Deposits or withdrawals of our shares by US Holders in exchanges for ADSs will not result in the realization of gain or loss for US federal income tax purposes.

United States Information Reporting and Backup Withholding. Dividend payments with respect to shares or ADSs and proceeds from the sale, exchange or other disposition of shares or ADSs received in the United States or through US-related financial intermediaries, may be subject to information reporting to the IRS and possible US backup withholding. Certain exempt recipients (such as corporations) are not subject to these information reporting and backup withholding requirements. Backup withholding will not apply to a US Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. Any US Holders required to establish their exempt status generally must provide a properly-executed IRS Form W-9 (Request for Taxpayer Identification Number and Certification). Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a US Holder's US federal income tax liability, and a US Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

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10.6	Divide	nds an	d paving	agents

Not applicable.

#### 10.G Statement by experts

Not applicable.

### 10.H Documents on display

Any statement in this Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Form 20-F the contract or document is deemed to modify the description contained in this Form 20-F. You must review the exhibits themselves for a complete description of the contract or document.

You may review a copy of our filings with the SEC, as well as other information furnished to the SEC, including exhibits and schedules filed with it, at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In

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addition, the SEC maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the SEC. These SEC filings are also available to the public from commercial document retrieval services.

We are required to file or furnish reports and other information with the SEC under the Securities Exchange Act of 1934 and regulations under that act. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the form and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short swing profit recovery provisions contained in Section 16 of the Exchange Act.

#### 10.I Subsidiary Information

Not applicable.

#### Item 11. Quantitative and Qualitative Disclosures about Market Risk

The major financial risks facing the Group are managed centrally by Group Treasury. We have a written Treasury Policy and have implemented a strict segregation of front office and back office controls. The Group does regular reconciliations of its positions with its counterparties. In addition the Treasury function is included in management's internal control assessment.

For information about the effects of currency fluctuations and how we manage currency risk, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Effects of Currency Fluctuations", "Item 5.A Operating Results Currency Impact on Key Figures" and "Item 5.B Liquidity and Capital Resources".

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For further information, see "Item 18. Financial Statements" note 16".

#### Item 12. Description of Securities other than Equity Securities

12.A Debt Securities	
Not applicable.	
12.B Warrants and Rights	
Not applicable.	
12.C Other Securities	
Not applicable.	

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# 12.D American Depositary Shares

# Fees Payable By ADS Holders

According to our Deposit Agreement with the ADS depositary, JPMorgan Chase Bank (JPMorgan), holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth below:

Category Depositing or substituting underlying shares	Depositary actions Acceptance of shares surrendered, and issuance of ADSs in exchange, including surrenders and issuances in respect of: Share distributions Stock split Rights Merger Exchange of shares or any other transaction or event or other distribution affecting the ADSs or the deposited shares	Associated Fee \$5.00 for each 100 ADSs (or portion thereof) evidenced by the new ADSs delivered
Withdrawing underlying shares	Acceptance of ADSs surrendered for withdrawal of deposited shares	\$5.00 for each 100 ADSs (or portion thereof) evidenced by the ADSs surrendered
Selling or exercising rights	Distribution or sale of shares, the fee being in an amount equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such shares	\$5.00 for each 100 ADSs (or portion thereof)
Transferring, splitting or grouping receipts	Transfers, combining or grouping of depositary receipts	\$2.50 per ADS
Expenses of the depositary	Expenses incurred on behalf of holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment the depositary's or its custodian's compliance with applicable law, rule or regulation. stock transfer or other taxes and other governmental charges cable, telex and facsimile transmission and delivery expenses of the depositary in connection with the conversion of foreign currency into US dollars (which are paid out of such foreign currency) any other charge payable by any of the depositary or its agents	Expenses payable at the sole discretion of the Depositary by billing Holders or by deducting charges from one or more cash dividends or other cash distributions.
Advance tax relief	Tax relief/reclamation process for qualified holders.	A depositary service charge of \$0.0035 per ADS

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### Fees Payable By The Depositary To The Issuer

Pursuant to an agreement effective as of May 11, 2012, JPMorgan, as depositary, has agreed to reimburse Novartis \$1.0 million per quarter, a total of \$4.0 million per contract year, for expenses incurred directly related to our ADS program (the "Program") which were incurred during the contract year, including Program-related legal fees, expenses related to investor relations in the US, US investor presentations, ADS-related financial advertising and public relations, fees and expenses of JPMorgan as administrator of the ADS Direct Plan, reasonable accountants' fees in relation to our Form 20-F, maintenance and broker reimbursement expenses. Because our expenses related to these categories exceed \$4.0 million (see, for example, the amount of our accountants' fees set forth at "Item 16C. Principal Accountant Fees and Services Auditing and Additional Fees"), the \$4.0 million cannot be deemed to have reimbursed us for any particular one or more of these expenses.

JPMorgan has further agreed not to seek reimbursement of up to \$50,000 of out-of-pocket expenses incurred annually in providing such administrative services.

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#### Part II

#### Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

#### Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

None.

#### Item 15. Controls and Procedures

- (a) Novartis AG's chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective.
- (b) Report of Novartis Management on Internal Control Over Financial Reporting: Novartis' Board of Directors and management of the Group are responsible for establishing and maintaining adequate internal control over financial reporting. The Group's internal control system was designed to provide reasonable assurance to the Group's management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of its published consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Group management assessed the effectiveness of the Group's internal control over financial reporting as of December 31, 2012. In making this assessment, it used the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our assessment management concluded that, as of December 31, 2012, Group's internal control over financial reporting is effective based on those criteria.

PricewaterhouseCoopers AG, Switzerland (PwC), an independent registered public accounting firm, has issued an opinion on the effectiveness of the Group's internal control over financial reporting which is included under "Item 18. Financial Statements" on page F-2.

- (c) See the report of PwC, an independent registered public accounting firm, included under "Item 18. Financial Statements" on page F-2.
- (d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 16A. Audit Committee Financial Expert

Our Audit and Compliance Committee has determined that Srikant Datar and Ulrich Lehner each possess specific accounting and financial management expertise and that each is an Audit Committee Financial Expert as defined by the US Securities and Exchange Commission (SEC). The Board of Directors has also determined that other members of the Audit and Compliance Committee have

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sufficient experience and ability in finance and compliance matters to enable them to adequately discharge their responsibilities.

#### Item 16B. Code of Ethics

In addition to our Code of Conduct, which is applicable to all of our associates, we have adopted a Code of Ethical Conduct that imposes additional obligations on our principal executive officer, principal financial officer, principal accounting officer, and persons performing similar functions. This document is accessible on our Internet website at

http://www.novartis.com/investors/corporate-governance.shtml

### Item 16C. Principal Accountant Fees and Services

Refer to "Item 6. Directors, Senior Management and Employees Item 6.C Board Practices The Independent External Auditors."

#### Item 16D. Exemptions from the Listing Standards for Audit Committees

Not Applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchaser