NOVARTIS AG
Form 20-F
January 23, 2013

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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)

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

Title of class	Name of each exchange on which registered
American Depositary Shares each representing 1 share, nominal value CHF 0.50 per share, and shares	**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	2008
	($ 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**
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					70
Basic earnings per share ($):					
Continuing operations	3.93	3.83	4.28	3.70	3.59
Discontinued operations					0.03
Total	3.93	3.83	4.28	3.70	3.62
Diluted earnings per share ($):					
Continuing operations	3.89	3.78	4.26	3.69	3.56
Discontinued operations					0.03
Total	3.89	3.78	4.26	3.69	3.59
Cash dividends[(1)]	6,030	5,368	4,486	3,941	3,345
Cash dividends per share in CHF[(2)]	2.30	2.25	2.20	2.10	2.00

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

(2) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 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

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.

Year Earned	Month and Year Paid	Total Dividend per share (CHF)	Total Dividend per share ($)
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]

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

(2) 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,				
($ 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
Month				
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 850,000 patients. Novartis will also intensify efforts to build a multi-stakeholder initiative in a final push against leprosy. We have a long history in fighting leprosy, donating medicines and developing programs to support patients, valued at more than $100 million since 1986.
	Novartis announces the restructuring of its US Pharmaceuticals business to strengthen its competitive position in light of the loss of patent protection for *Diovan* and the expected impact on the worldwide sales of *Tekturna/Rasilez* after the termination of the ALTITUDE study. The restructuring of the US General Medicines business results in a reduction of 1,960 positions and leads to an exceptional charge of $160 million in the first quarter of 2012 and to expected annual savings of approximately $450 million by 2013.

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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:

- Oncology
- Primary Care
  - Primary Care medicines
  - Established Medicines
- Specialty 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	**Product**	**Common name**	**Indication[1]**	**Formulation**
Oncology	*Afinitor/Votubia*	everolimus	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	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 *Gleevec/Glivec* 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	Product	Common name	Indication[1]	Formulation
[1] Indications vary by country.				
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 *Candida* Onychomycosis of the toenail or fingernail due to dermatophytes	DermGel Solution Spray

(1) Indications vary by country.

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Business franchise	Product	Common name	Indication[1]	Formulation
	Lescol/ Lescol XL	fluvastatin sodium	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	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

[1] Indications vary by country.

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Business franchise	Product	Common name	Indication[(1)]	Formulation
Specialty Care				
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$_2$-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	**Common name**	**Mechanism of action**	**Potential indication/ Disease area**	**Business franchise**	**Formulation/ Route of administration**	**Year Project Entered Current Development Phase**	**Planned filing dates/Current phase**
ACZ885	canakinumab	Anti IL-1β monoclonal antibody	Gouty arthritis	Integrated Hospital Care	Subcutaneous injection	EU: 2010 US: 2011	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					
BAF312	siponimod	Sphingosine-1-phosphate (S1P) receptor modulator	Multiple sclerosis	Neuroscience	Tablet	2012	≥2017/III
BCT197	TBD	Anti-inflammatory agent	Chronic obstructive pulmonary disease	Primary Care	Oral	2011	≥2017/II
BEZ235	TBD	P13K/mTOR inhibitor	Solid tumors	Oncology	Oral	2010	≥2017/II
BGS649	TBD	Aromatase inhibitor	Obese hypogonadotropic hypogonadism	Critical Care	Oral	2010	≥2017/II
BKM120	TBD	P13K inhibitor	Breast cancer	Oncology	Oral	2011	2015/III
			Solid tumors			2011	≥2017/I
BYL791	TBD	P13K inhibitor	Solid tumors	Oncology	Tablet	2010	≥2017/I
BYM338	TBD	Inhibitor of Activin receptor Type II	Sporadic Inclusion Body Myositis	Integrated Hospital Care	Intravenous infusion	2012	2016/II
CAD106	TBD	Beta-amyloid-protein immunotherapy	Alzheimer's disease	Neuroscience	Subcutaneous, intramuscular injection	2008	≥2017/II

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Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
CTL019	TBD	CD19-targeted chimeric antigen receptor (CAR) T-cell immunotherapy	Leukemia	Oncology	Intravenous	2012	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	**Common name**	**Mechanism of action**	**Potential indication/ Disease area**	**Business franchise**	**Formulation/ Route of administration**	**Year Project Entered Current Development Phase**	**Planned filing dates/Current phase**
QMF149	indacaterol and mometasone furoate	Long-acting beta2- agonist and inhaled corticosteroid	Chronic obstructive pulmonary disease	Primary Care	Inhalation	2007	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 $beta_2$-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 $beta_2$-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	Potential indication/ Disease area	Change	Reason
AEB071	Prevention of organ rejection after transplantation kidney and liver	Terminated	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 *Jakavi.*
	Polycythemia vera		

		Now disclosed under the brand name *Jakavi*	
KAE609	Malaria	Added	Entered confirmatory development

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Project/Product	Potential indication/ Disease area	Change	Reason
LCI699	Solid tumors	Now disclosed as Cushing's disease	
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**

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

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

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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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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[2] $ millions	$ millions	Core R&D[2] $ millions	$ millions	Core R&D[2] $ millions
Research and Exploratory 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**

(1) 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.

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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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)
Ear Infections	*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)

* 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

Franchise	Project/Compound	Condition	Planned filing dates	Current phase
Surgical	*AcrySof IQ ReSTOR* IOL (new design)	Cataract	US 2013 EU 2012 Jpn 2013	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[(1)] 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

Luxite microscope	Cataract	US 2013 EU 2013 Jpn 2014	Advanced development

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

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Franchise	Project/Compound	Condition	Planned filing dates	Current phase
Ophthalmic Pharmaceuticals	*Azorga* solution	Glaucoma	Jpn 2012	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 *Diovan*/*Co-Diovan*)

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

Product	Originator Drug	Description
Carboplatin	Paraplatin®	Ovarian, lung, head-neck and cervix cancer
Epirubicin	Farmorubicin®	Breast, lung, ovarian, gastric and bladder cancer, and others
Gemcitabine	Gemzar®	Bladder, pancreas, lung, ovarian, and breast cancer
Methotrexate	Folex®, Rheumatrex®	Arthritis; breast, lung, cervix and ovarian cancer, and others
Oxaliplatin	Eloxatin®	Colorectal and colon cancer
Paclitaxel	Taxol®	Breast, lung and ovarian cancer, Kaposi sarcoma
Docetaxel	Taxotere®	Breast, ovarian and non-small cell lung cancer

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**

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

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.

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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 *MF59* 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[(1)]	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[(2)]	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

(1) In collaboration with Intercell.

(2) In collaboration with Crucell.

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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
Procleix Ultrio Elite Assay	Highly sensitive NAT assay to detect HIV-1, HIV-2, HCV and HBV on the *Procleix Panther* platform
Procleix Ultrio Plus Assay	Highly sensitive NAT assay to detect HIV-1, HCV and HBV on the *Procleix Tigris* 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
Blood Screening	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**

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

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 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.

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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 *Sentinel/Milbemax/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

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.

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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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[(1)]

(1) 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.

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2012 Compared to 2011

Key Figures

	Year ended Dec 31, 2012	Year ended Dec 31, 2011	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales	**56,673**	**58,566**	**(3)**	**0**
Other revenues	888	809	10	11
Cost of goods sold	(18,756)	(18,983)	(1)	2
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**
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.

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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	Year ended Dec 31, 2011	Change in $	Change in constant currencies
	$ m	$ m	%	%
Established Markets*	**42,834**	**44,774**	**(4)**	**(2)**
Emerging Growth Markets*	**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.

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TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2012

Brands	Business franchise	Indication	Net sales United States	Change in constant currencies	Net sales Rest of world	Change in constant currencies	Total net sales	Change in $	Change in constant currencies
			$ m	%	$ m	%	$ m	%	%
Gleevec/Glivec	Oncology	Chronic myeloid leukemia	1,698	16	2,977	(2)	**4,675**	**0**	**4**
Diovan/Co Diovan	Primary care	Hypertension	2,087	(11)	2,330	(28)	**4,417**	**(22)**	**(21)**
Lucentis	Ophthalmics	Age-related macular degeneration			2,398	22	**2,398**	**17**	**22**
Sandostatin	Oncology	Acromegaly	649	13	863	5	**1,512**	**5**	**8**
Exforge	Primary care	Hypertension	358	10	994	18	**1,352**	**12**	**16**
Zometa	Oncology	Cancer complications	561	(13)	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	38	647	47	**998**	**39**	**44**
Galvus	Primary care	Diabetes			910	43	**910**	**34**	**43**
Exjade	Oncology	Iron chelator	251	(3)	619	11	**870**	**2**	**7**
Neoral/Sandimmun	Integrated Hospital Care	Transplantation	64	(10)	757	(6)	**821**	**(9)**	**(6)**
Afinitor/Votubia	Oncology	Breast cancer	412	142	385	49	**797**	**80**	**85**
***Voltaren* (excl. OTC)**	Additional products	Inflammation/pain	1	(75)	758	1	**759**	**(4)**	**0**
Reclast/Aclasta	Established medicines	Osteoporosis	354	(8)	236	9	**590**	**(4)**	**(2)**
Myfortic	Integrated Hospital Care	Transplantation	239	20	340	14	**579**	**12**	**16**
Ritalin/Focalin	Additional products	Attention deficit/ hyperactivity disorder	402	1	152	8	**554**	**1**	**3**
Comtan/Stalevo	Neuroscience	Parkinson's disease	147	(31)	383	0	**530**	**(14)**	**(11)**
Xolair	Critical Care	Asthma			504	15	**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)**
Total Division sales			**10,392**	**4**	**21,761**	**1**	**32,153**	**(1)**	**2**

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.

Reclast/*Aclasta* ($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 $beta_2$-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.

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Alcon division net sales by product category:

	Year ended Dec 31, 2012 $ m	Year ended Dec 31, 2011 $ m	Change in $ %	Constant currencies change %
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	% of net sales	Year ended Dec 31, 2011	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
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	% of net sales	Year ended Dec 31, 2011	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
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 *Tekturna*/*Rasilez* 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	Core R&D 2012[1]	2011	Core R&D 2011[1]
	$ m	$ m	$ m	$ 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**

(1) Core excludes impairments, amortization and other exceptional items.

Alcon

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 $ m	Year ended Dec 31, 2011 $ m	Change in $ %	Change in constant currencies %
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 $ m	2011 $ 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	Year ended Dec 31, 2010	Change in $	Change in constant currencies
	$ m	$ m	%	%
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)**
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)**

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Core Key Figures

	Year ended Dec 31, 2011 $ m	Year ended Dec 31, 2010 $ m	Change in $ %	Change in constant currencies %
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[1]	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**

(1) 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

Brands	Business Franchise	Indication	Net sales United States	Change in constant currencies	Net sales rest of world	Change in constant currencies	Total net sales	Change in $	Change in constant currencies
			$ 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	1,459	14	3,200	2	4,659	9	5
Lucentis	Ophthalmics	Age-related macular degeneration			2,050	26	2,050	34	26
Zometa	Oncology	Cancer 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 Hospital Care	Transplantation	71	(13)	832	(1)	903	4	(2)
Exjade	Oncology	Iron chelator	259	(2)	591	13	850	12	8
Voltaren (excl. OTC)	Additional products	Inflammation/pain	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 medicines	Osteoporosis	386	(2)	227	18	613	6	5
Tekturna/Rasilez	Primary care	Hypertension	216	4	341	41	557	27	24
Ritalin/Focalin	Additional products	Attention Deficit/Hyperactive Disorder	398	17	152	14	550	19	17
Myfortic	Integrated Hospital Care	Transplantation	200	23	318	11	518	17	15
Gilenya	Neuroscience	Relapsing Multiple 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	(9)	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 ($103 million) has shown strong sales growth since its approval in the EU in November 2009 as a once-daily long-acting beta$_2$-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.

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Alcon division pro forma net sales by product category:

	Year ended Dec 31, 2011	Year ended Dec 31, 2010	Change in $	Constant currencies 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 *Patanol/Pataday* 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[1]	% 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**	**(7)**	**4**
Corporate income & expenses, net	(670)		(452)			
Operating income	**10,998**	**18.8**	**11,526**	**22.8**	**(5)**	**1**

(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	% of net sales	Year ended Dec 31, 2010[1]	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
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**

(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".

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 *Tekturna/Rasilez* 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