NOVARTIS AG
Form 20-F
January 25, 2012

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As filed with the Securities and Exchange Commission on January 25, 2012

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, 2011

OR

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

OR

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

Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

Lichtstrasse 35
4056 Basel, Switzerland

(Address of principal executive offices)

Felix R. Ehrat
Group General Counsel

Novartis AG
CH-4056 Basel
Switzerland
011-41-61-696-9511
felix.ehrat@novartis.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class	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:

2,406,693,857 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 nor is any Group company the agent of any other 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; or regarding potential future sales or earnings of the Novartis Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements 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, or any of its divisions, will achieve any particular financial results. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including the potential outcomes of our ongoing discussions with health authorities concerning *Rasilez/Tekturna* as a result of the ALTITUDE study, and including the outcome of health authority reviews of the benefits and risks of *Gilenya;* unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data, including any potential new analyses of the ALTITUDE study which may occur; 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 issues, including the potential outcomes of the Warning Letter issued to us with respect to three Sandoz manufacturing facilities, and the potential outcome of the shutdown of the OTC 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 regarding sales and marketing practices, shareholder litigation, government investigations and intellectual property disputes; competition in general; uncertainties regarding the

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after-effects of the recent global financial and economic crisis; uncertainties regarding future global exchange rates and uncertainties regarding future demand for our products; 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, 2011, 2010 and 2009 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,				
	2011	**2010**	**2009**	**2008**	**2007**
	($ millions, except per share information)				
INCOME STATEMENT DATA					
Net sales from continuing operations	**58,566**	**50,624**	**44,267**	**41,459**	**38,072**
Operating income from continuing operations	**10,998**	**11,526**	**9,982**	**8,964**	**6,781**
Income from associated companies	528	804	293	441	412
Interest expense	(751)	(692)	(551)	(290)	(237)
Financial income/(expense)	(2)	64	198	384	531
Income before taxes from continuing operations	**10,773**	**11,702**	**9,922**	**9,499**	**7,487**
Taxes	(1,528)	(1,733)	(1,468)	(1,336)	(947)
Net income from continuing operations	**9,245**	**9,969**	**8,454**	**8,163**	**6,540**
Net income from discontinued operations				70	5,428
Group net income	**9,245**	**9,969**	**8,454**	**8,233**	**11,968**
Attributable to:					
Shareholders of Novartis AG	9,113	9,794	8,400	8,195	11,946
Non-controlling interests	132	175	54	38	22
Operating income from discontinued operations (including divestment gains)				70	6,152
Basic earnings per share ($):					
Continuing operations	3.83	4.28	3.70	3.59	2.81
Discontinued operations				0.03	2.34
Total	3.83	4.28	3.70	3.62	5.15
Diluted earnings per share ($):					
Continuing operations	3.78	4.26	3.69	3.56	2.80
Discontinued operations				0.03	2.33
Total	3.78	4.26	3.69	3.59	5.13
Cash dividends[1]	5,368	4,486	3,941	3,345	2,598
Cash dividends per share in CHF[2]	2.25	2.20	2.10	2.00	1.60

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

(2) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2011 will be proposed to the Annual General Meeting on February 23, 2012 for approval.

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	Year Ended December 31,				
	2011	2010	2009	2008	2007
			($ millions)		
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial instruments	5,075	8,134	17,449	6,117	13,201
Inventories	5,930	6,093	5,830	5,792	5,455
Other current assets	13,079	12,458	10,412	8,972	8,774
Non-current assets	93,412	96,633	61,814	57,418	48,022
Total assets	**117,496**	**123,318**	**95,505**	**78,299**	**75,452**
Trade accounts payable	4,989	4,788	4,012	3,395	3,018
Other current liabilities	18,159	19,870	15,458	13,109	13,623
Non-current liabilities	28,408	28,891	18,573	11,358	9,415
Total liabilities	**51,556**	**53,549**	**38,043**	**27,862**	**26,056**
Issued share capital and reserves attributable to shareholders of Novartis AG	65,844	63,196	57,387	50,288	49,223
Non-controlling interests	96	6,573	75	149	173
Total equity	**65,940**	**69,769**	**57,462**	**50,437**	**49,396**
Total liabilities and equity	**117,496**	**123,318**	**95,505**	**78,299**	**75,452**
Net assets	65,940	69,769	57,462	50,437	49,396
Outstanding share capital	895	832	825	820	815
Total outstanding shares (millions)	2,407	2,289	2,274	2,265	2,264

Cash Dividends per Share

Cash dividends are translated into US dollars at the Reuters 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 ($)
2007	February 2008	1.60	1.53
2008	February 2009	2.00	1.72
2009	March 2010	2.10	1.95
2010	March 2011	2.20	2.37
2011[1]	March 2012	2.25	2.39[2]

(1) Dividend to be proposed at the Annual General Meeting on February 23, 2012 and to be distributed March 1, 2012.

(2) Translated into US dollars at the 2011 Reuters Market System period end rate of $1.06 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 Market System. The exchange rate in effect on January 19, 2012, as found on Reuters Market System, was CHF 1.00 = $1.07.

Year ended December 31, ($ per CHF)	**Period End**	**Average[1]**	**Low**	**High**
2007	0.88	0.83	0.80	0.91
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
Month				
August 2011			1.22	1.37
September 2011			1.10	1.27
October 2011			1.08	1.16
November 2011			1.08	1.13
December 2011			1.05	1.10
January 2012[2]			1.05	1.07

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

(2) Through January 19, 2012.

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 will continue in the US in 2012 and in Japan in 2013 will have a material adverse effect

on our results of operations.

The introduction of generic competition for a patented medicine typically results in a significant and rapid reduction in net sales 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

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class as one of our drugs, or in another competing therapeutic class. 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, or 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 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 is scheduled to expire in the US in September 2012, and in Japan in 2013. The active ingredient valsartan is also used in the single-pill combination therapies *Exforge/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 in the US 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), will expire in 2013 in the US and in 2012 and 2013 in other major markets.

The patent on *Glivec/Gleevec* (cancer) will expire in 2015 in the US, in 2016 in the major EU countries and 2014 in Japan, in each case including extensions.

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".

Clearly, with respect to major products for which the patent terms are expiring, the loss of exclusivity of these products will have a material adverse effect on our business, financial condition and results of operations. In addition, should we unexpectedly lose exclusivity on additional products due to patent litigation or other reasons, this will also have a material adverse effect on our business, financial condition and results of operations, both due to the loss of revenue, and the difficulties in planning for such losses.

Our research and development efforts may not succeed in bringing high-potential products to market, or to do so cost-efficiently enough, or in sufficient numbers.

Our ability to continue to grow our business and to replace sales lost due to the end of market exclusivity depends upon the success of our research and development activities in identifying, and successfully and cost-effectively developing high-potential breakthrough 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 a sufficient number of commercially viable new products.

Using the products of our largest 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

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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 of other safety concerns; insufficient clinical trial data to support the safety or efficacy of the product candidate; our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient 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' compliance with regulations related to the development of new products, thus adding to the obstacles and costs we face in bringing new products to market.

Our Vaccines and Diagnostics and Alcon Divisions face challenges similar to those faced by our Pharmaceuticals Division in developing and bringing to market new products. At Alcon, management has announced plans to make significant investments in research and development in the coming years to develop new eyecare products. Vaccines and Diagnostics has, and continues to expend considerable time and resources to fully develop and bring to market two vaccines, *Menveo* and *Bexsero*, to combat different strains of meningococcal disease in patients of a wide range of age groups. These products are the primary products in the Vaccines and Diagnostics Division's pipeline. If these efforts by our Alcon and Vaccines and Diagnostics Divisions 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 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 somewhat less costly and complex than the development of originator biologic medicines, to date many countries do not yet have an established legislative or regulatory pathway which would permit such products to be sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Significant delays in the development of such pathways, or significant impediments that may ultimately be built into such pathways, could diminish the value of the investments that Sandoz has made, and will continue to make, in its biotechnology operations, and could have a material adverse effect on the long-term success of 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 to replace sales lost as older products are lost 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 several widely publicized issues in recent years, health regulators are increasingly focusing on product safety. Recently, the Obama Administration has publicly emphasized the importance of enforcing US drug safety regulations. In addition, authorities have paid increased attention to the risk/benefit profile of pharmaceutical products with an increasing emphasis on product safety and the value-added of products. These developments have led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals for pharmaceutical products has become even more challenging.

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

Like our industry peers, we have been required by health authorities to conduct additional clinical trials, and to submit additional analyses of our data in order to obtain product approvals. 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

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delays in obtaining approvals and creating a risk that safe and efficacious products will not be approved, or will be removed from the market after previously having been approved these regulatory developments have had, and likely will 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 spending even more tightly. These pressures are particularly strong given the lingering effects of the recent global economic and financial crisis, including the ongoing 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 initiatives, 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, payors limiting access to innovative medicines on their own cost-benefit analyses, 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 2011. For example, in April, Italy introduced temporary price cuts with the aim of saving $834 million by the end of 2011, and Germany increased their mandatory rebates from 6 to 10%. Other European countries exerting price pressure include France and Portugal. In the United States, an uncertain economy and regulatory reform continued to weigh on the industry. In addition, during 2011, the UK's National Institute for Health and Clinical Excellence (NICE) declined on cost-effectiveness grounds to recommend UK National Health Service funding of use of our product *Afinitor* for advanced renal cell carcinoma, and the use of our product *Lucentis* to treat diabetic macular edema, and issued negative draft guidance in relation to the use of our product *Gilenya* and of our product *Lucentis* to treat macular edema caused by retinal vein occlusion, despite the products having been approved by the relevant health authorities for each of the indications.

We expect these efforts to control costs to continue in 2012 as healthcare payors around the globe in particular government-controlled health authorities, insurance companies and managed care organizations step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price cuts. For more information on price controls and on our challenging business environment see "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls."

Failure to comply with law, and resulting 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 operate, covering an extremely wide range of activities. To that end, we have a significant global compliance with law program in place. Nonetheless, despite our efforts, any failure to comply with 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 litigation and government investigations 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 and trade restrictions. Responding to such investigations is costly, and a significant

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diversion of management's attention from our business. In addition, such investigations may affect our reputation and create a risk of potential exclusion from government reimbursement programs in the US and other countries. These factors have contributed to decisions by us and other companies in our industry to enter into settlement agreements with governmental authorities around the world. Those settlements have involved and may continue to involve large cash payments, including the potential repayment of amounts allegedly obtained improperly and penalties up to treble damages. In addition, settlements of healthcare fraud cases often require companies to enter into a corporate integrity agreement, which is 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 have been subject, from time to time, to governmental investigations and information requests by regulatory authorities. In 2010 our US affiliate Novartis Pharmaceuticals Corporation (NPC) settled parallel civil and criminal investigations by the US government into allegations of potential inappropriate marketing and promotion of six Novartis drugs. As part of the settlement, NPC agreed to plead guilty to one misdemeanor, and to resolve civil charges against it, agreeing to pay a total of $422.5 million, and to enter into a five-year Corporate Integrity Agreement.

At the same time, 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 these cases 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.

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 there could be a regulatorily-required shutdown of production facilities or production lines, which in turn could lead to product shortages, or to our being entirely unable to supply product to patients for an extended duration. This, in turn, could lead to a significant loss of sales revenue and potential third-party litigation. In addition, health authorities have begun to impose 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 which remains unresolved. The Warning Letter raised concerns regarding these facilities' compliance with FDA cGMP regulations. 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. However, 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.

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Similarly, in December 2011, 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 plan to gradually resume operations at the Lincoln site following implementation of planned improvements and in agreement with the FDA. However, as of the date of this Form 20-F, it is not possible to determine when the plant will resume full operations. The Lincoln facility produces a variety of products with annual sales value of less than 2% of Novartis Group sales. Should we fail to complete the planned improvements at the site in agreement with the FDA in a timely manner, then we may suffer a significant loss in sales.

In addition, we currently have several other Group Company manufacturing sites which are being upgraded to address advances in technology, improve quality, and assure consistency of product supply, in accordance with commitments to FDA. Ultimately, there can be no guarantee of the outcome 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, an increasing portion of our portfolio, including products from our Pharmaceuticals, Alcon, Vaccines and Diagnostics, and Sandoz Divisions, are "biologic" products. Unlike traditional "small-molecule" drugs, biologic drugs or other biologic-based products cannot be manufactured synthetically, but typically must be produced from living plant or animal micro-organisms. As a result, the production of biologic-based products which meet all regulatory requirements is especially complex. Even slight deviations at any point in the production process may lead to batch failures or recalls. In addition, because the production process is based on living 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. Any change in the environment may impact production schedules and inadvertently affect supply until remediated. For example, drug shortages were reported for a limited period of time this year for influvite, which is produced at the Sandoz, Boucherville, Canada site.

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 ability to raise capital. 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. 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 deteriorate as a result of potential developments in countries of key concern such as Greece, which is facing possible default of its sovereign debt obligations, as well as Spain and Italy, the sovereign debt obligations of which were recently downgraded.

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 negatively impact our business and cash flow. Although we attempt 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

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bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to 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 and currencies of different countries has impacted, and may continue to unpredictably impact, the conversion of our operating results into US dollars, our reporting currency. This is particularly so given recent financial troubles in the US and in many European economies, investor concerns about the future of the Euro, and the flight of investor capital to the perceived safety of the Swiss franc. The financial and debt crises may also cause the value of our investments in our pension plans to decrease, potentially requiring us to increase our funding of those pension plans. 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. See also " 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, and " Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets" below.

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 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 suffered significant decreases in value against other world currencies. Because a significant portion of our earnings and expenditures are in currencies other than the US dollar, these decreases have had a significant impact on our reported net sales and earnings. In 2011, 36% of our net sales were made in US dollars, 27% in euros, 9% in Japanese yen, 2% in Swiss francs and 26% in other currencies. During the same period, 38% of our expenses arose in US dollars, 25% in euros, 14% in Swiss francs, 4% in Japanese yen and 19% 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. 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. 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 11. Quantitative and Qualitative Disclosures about Non-Product-Related Market Risk." See also " The continuing economic and financial crisis may have a material adverse effect on our results" above.

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, 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

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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. In 2011, for example, we recorded intangible asset impairment charges of $619 million. Of these charges, $552 million arose in the Pharmaceuticals Division, principally due to the expected reduction in demand for *Tekturna/Rasilez* (aliskiren), and discontinuation of the PRT128 (elinogrel), SMC021 (oral calcitonin), PTK796 (omadacycline) and AGO178 (agomelatine) development programs. $67 million of impairment charges arose 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, 2011 we had $13.8 billion of non-current financial debt and $6.4 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 places 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.

Our reliance on 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. We do not control the third parties to whom we outsource these functions, but we depend on them to achieve results which may be significant to us. If these third parties fail to meet our expectations, 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 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 pharmaceuticals in industrialized countries, many emerging markets have experienced comparatively strong economies, leading to proportionately higher growth and an increasing

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contribution to the industry's global performance. In 2011, we generated $5.8 billion, or approximately 10% (2010: 10%) of net sales from our six priority emerging markets Brazil, China, India, Russia, South Korea and Turkey as compared with $37 billion, or approximately 63% (2010: 64%) of our net sales, in the world's seven largest developed markets. However, combined net sales in the six priority emerging markets grew 17% in constant currency in 2011, compared to 11% sales growth in constant currency in the seven largest developed markets during the same period. As a result of this trend, we have been taking steps to increase our presence in these priority emerging markets and in other emerging markets. For example, in June 2011, we began construction on a new state-of-the-art manufacturing plant for pharmaceutical and generic medicines in St. Petersburg, Russia. This investment is part of a greater commitment to local infrastructure and collaborative healthcare initiatives planned in Russia over a five-year period. In China, by 2014 we will expand the number of our research and development associates nearly ten-fold, bringing the total to 1,200 across all divisions.

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 countries may be especially vulnerable to the after-effects of the recent 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 many emerging countries, we may be required to rely on third-party agents, which may put us at risk of liability. See " Legal proceedings may have a significant negative effect on our results of operations" above. In addition, many of these countries have currencies that fluctuate substantially. If currencies devalue and we cannot offset the devaluations with price increases, 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 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. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction.

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.

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, expected returns on plan assets 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-half of one percent would have increased our year-end defined benefit obligation by $1.3 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Retirement and other

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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 reduce the effective tax rate on our earnings because a portion of our earnings are taxed at more favorable rates in some jurisdictions. Changes in tax laws or their application with respect to matters such as 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.

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 9%, 7% and 7%, respectively, of Group net sales in 2011. The largest trade receivables outstanding were for these three customers, amounting to 10%, 6% and 6%, respectively, of the Group's trade receivables at December 31, 2011. The 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

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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.

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."

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 either the rules that apply to such communications, or 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. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition and results of operations.

Earthquakes could adversely affect our business.

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 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.

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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 any 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 cash 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 granting of 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 and Sandoz, 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

The Novartis Group 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, 100% of most significant operating companies. For a list of our significant operating subsidiaries, see "Item 18. Financial Statements note 31."

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Important Corporate Developments 2009-2011

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.

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 the portfolio of our Molecular Diagnostics unit 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.

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	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 approx $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 sale 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.
2009	
December	Novartis enters into an agreement to acquire Corthera Inc. for $120 million plus potential milestone payments related to the successful development and commercialization of relaxin, a potential treatment for acute decompensated heart failure. The acquisition was completed in February 2010.
	Novartis licenses to Prometheus Laboratories the rights to sell *Proleukin* in the US, commencing in February 2010. Novartis retains the right to sell *Proleukin* outside of the US.
November	Novartis announces $1 billion investment over the next five years to significantly expand the China Novartis Institutes for BioMedical Research so that it would become the largest pharmaceutical research and development institute in China, and the third largest Novartis research institute worldwide.
	Novartis enters into agreement to acquire 85% stake in Chinese vaccines company Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd., which offers marketed vaccine products in China and research and development projects focused on viral and bacterial diseases, for $125 million.

Novartis opens large-scale flu cell culture vaccine and adjuvant manufacturing facility in Holly Springs, North Carolina, in partnership with US Department of Health and Human Services, Biomedical Research and Development Authority.

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	Novartis announces agreement to obtain rights outside the US to INC424, a promising Janus kinase inhibitor in Phase III development as well as worldwide rights to potential c-Met inhibitor compound, from Incyte Corporation for a combined upfront payment of $150 million as well as an immediate $60 million milestone payment and rights to potential future milestone payments and royalties based on future sales.
October	Novartis gains exclusive worldwide rights to PTK796, a potential first-in-class IV and oral broad-spectrum antibiotic in Phase III development, from Paratek Pharmaceuticals for upfront payment and eligibility for future milestone payments as well as royalties based on future sales.
	Novartis enters into agreement for exclusive US and Canadian rights to *Fanapt*, an FDA-approved oral therapy for schizophrenia, with Vanda Pharmaceuticals Inc. for an upfront payment of $200 million, eligibility for additional milestone payments and sales royalties.
June	Novartis completes an open offer to acquire an additional stake in its majority-owned Indian subsidiary, Novartis India Ltd., increasing its holding to nearly 76.4% from the previous level of 50.9%. The transaction represented a total value of approximately $80 million.
	Novartis successfully launches a EUR 1.5 billion notes issue.
May	Novartis signs definitive agreement to acquire for EUR 925 million ($1.3 billion) the specialty generic injectables business of EBEWE Pharma, providing Sandoz the Group's generics division an opportunity to create a global platform for growth while improving access for patients to many generic oncology medicines. The transaction closed in September.
February	Novartis gains worldwide rights to elinogrel (PRT128), a Phase II anti-clotting compound with potential to reduce risk of heart attack and stroke, from Portola Pharmaceuticals Inc. for an upfront payment of $75 million and rights to future milestone payments and royalties based on future sales.
	Novartis successfully completes a $5.0 billion debt offering in the US.

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 four 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. Novartis is the only company to have leadership positions in each of these areas.

The Group's wholly-owned 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

Our strategy is to strengthen our healthcare portfolio through sustained investments in innovation, as well as through targeted acquisitions.

Novartis achieved net sales of $58.6 billion in 2011, while net income amounted to $9.2 billion. We invested $9.6 billion ($9.1 billion excluding impairment and amortization charges) in Research & Development in 2011.

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Headquartered in Basel, Switzerland, our Group companies employed approximately 124,000 full-time equivalent associates as of December 31, 2011, and have operations in approximately 140 countries around the world.

Pharmaceuticals Division

Our Pharmaceuticals Division researches, develops, manufactures, distributes and sells patented prescription medicines in the following therapeutic areas (reorganized as of January 1, 2012): 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. In 2011, the Pharmaceuticals Division accounted for $32.5 billion, or 56%, of Group net sales, and for $8.3 billion, or 71%, of Group operating income (excluding Corporate income and expense, net).

Alcon Division

Our Alcon Division discovers, develops, manufactures, distributes and sells eye care products. Alcon is the global leader in eye care with product offerings in Surgical, Ophthalmic Pharmaceuticals and Vision Care. In Surgical, Alcon develops, manufactures, distributes and sells ophthalmic surgical equipment, instruments, disposable products and intraocular lenses. In Pharmaceutical, Alcon discovers, develops, manufactures, distributes and sells medicines to treat chronic and acute diseases of the eye, as well as over-the-counter medicines for the eye. In Vision Care, Alcon develops, manufactures, distributes and sells contact lenses and lens care products. In 2011, Alcon accounted for $10.0 billion, or 17%, of Group net sales, and for $1.5 billion, or 13%, of Group operating income (excluding Corporate income and expense, net).

Sandoz Division

Our Sandoz Division is a leading global generic pharmaceuticals company that 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. The Sandoz Division has activities in Retail Generics, Anti-Infectives, and Biopharmaceuticals & Oncology Injectables. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals, as well as supplying active ingredients to third parties. In Anti-Infectives, Sandoz develops and 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 biotech manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures and markets primarily cytotoxic products for the hospital market. In 2011, Sandoz accounted for $9.5 billion, or 16%, of Group net sales, and for $1.4 billion, or 12%, 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 vaccines and diagnostic tools. Novartis Vaccines is a leading global developer and manufacturer of human vaccines. Novartis Diagnostics is a blood testing and molecular diagnostics business dedicated to preventing the spread of infectious diseases through novel blood-screening tools that protect the world's blood supply. In 2011, the Vaccines and Diagnostics Division accounted for $2.0 billion, or 3%, of Group net sales, and an operating loss of $249 million.

Consumer Health

Consumer Health consists of two Divisions: OTC (over-the-counter medicines) and Animal Health. Each has its own research, development, manufacturing, distribution and selling capabilities. However, neither is material enough to the Group to be separately disclosed as a segment. OTC offers readily available consumer medicine. Animal Health provides veterinary products for farm and companion animals. In 2011, Consumer Health accounted for $4.6 billion, or 8%, of Group net sales, and for $727 billion, or 6%, of Group operating income (excluding Corporate income and expense, net).

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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; and Novartis Molecular Diagnostics, a business responsible for the development and commercialization of diagnostic tests and services related to our pharmaceuticals portfolio and therapeutic areas.

Prior to January 1, 2012, the therapeutic areas of the Pharmaceuticals Division were divided into the following franchises: Cardiovascular and Metabolism, Oncology (including Hematology), Neuroscience and Ophthalmics, Respiratory, Integrated Hospital Care, and Other additional products. The tables, product descriptions and other information set forth below in this Item 4.B reflect the new organization which took effect as of January 1, 2012. However, we continue to provide certain historical information elsewhere in this 20-F, including certain sales data, organized by the prior therapeutic areas.

The Pharmaceuticals Division is the largest contributor among the six divisions of Novartis and reported consolidated net sales of $32.5 billion in 2011, which represented 56% of the Group's net sales.

The division is made up of approximately 80 affiliated companies which together employed 60,527 full-time equivalent associates as of December 31, 2011, and sell products in approximately 140 countries. The product portfolio of the Pharmaceuticals Division includes more than 40 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, including recently launched 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 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 every country, or at all. 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. Certain 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.

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Key Marketed Products

Therapeutic area	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	Tablet
	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
	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
	Tasigna	nilotinib	Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec* First line CML	Capsule
	Zometa	zoledronic acid	Skeletal-related events from bone metastases (cancer that has spread to the bones) hypercalcemia of malignancy	Vial Ready-to-use

[1] Indications vary by country.

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Therapeutic area	Product	Common name	Indication[1]	Formulation
Primary Care				
Primary Care	*Amturnide*	aliskiren, amlodipine besylate and hydrochlorothiazide	Hypertension	Tablet
	Arcapta Neohaler/Onbrez Breezhaler	indacaterol	Chronic obstructive pulmonary disease	*Neohaler/Breezhaler* inhaler (powder in hard capsules for inhalation)
	Diovan	valsartan	Hypertension Heart failure Post-myocardial infarction	Capsule Tablet 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
	Tekturna/Rasilez	aliskiren	Hypertension	Tablet
	Tekturna HCT/Rasilez HCT	aliskiren and hydrochlorothiazide	Hypertension	Tablet
	Tekamlo/Rasilamlo	aliskiren and amlodipine besylate	Hypertension	Tablet
	Valturna	aliskiren and valsartan	Hypertension	Tablet

[1] Indications vary by country.

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Therapeutic area	Product	Common name	Indication[1]	Formulation
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
	Famvir	famciclovir	Acute herpes zoster including ophthalmic herpes zoster and decreased duration of post herpetic neuralgia Acute treatment of first episode and recurrent genital herpes infections, and for the suppression of recurrent genital herpes Treatment of recurrent herpes labialis (cold sores) Indicated in immuno- compromised patients with herpes zoster or herpes simplex infections	Tablet
	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	Fungal infection of the skin and nails caused by dermatophyte fungi Tinea capitis 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 (e.g. Candida albicans)	Tablet Cream DermGel Solution Spray
	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
	Lotensin/ Cibacen	benazepril hydrochloride	Hypertension Adjunct therapy in congestive heart failure Progressive chronic renal insufficiency	Tablet
	Lotensin HCT/ Cibadrex	benazepril hydrochloride and hydrochlorothiazide	Hypertension	Tablet
	Miacalcin/ Miacalcic	salmon calcitonin	Osteoporosis Bone pain associated with osteolysis and/or osteopenia Paget's disease Neurodystrophic disorders (synonymous with algodystrophy or Sudeck's disease) Hypercalcemia	Nasal spray Ampoule & multi-dose Vial for injection or infusion
	Reclast/ Aclasta	zoledronic acid/zoledronic acid 5 mg	Treatment of osteoporosis in postmenopausal women to reduce the incidence of hip, vertebral and non-vertebral fractures, and to increase bone mineral density Prevention of clinical fractures after hip fracture in men and 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

(1) Indications vary by country.

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Therapeutic area	Product	Common name	Indication[1]	Formulation
	Ritalin & Ritalin LA	methylphenidate HCl & methylphenidate HCl modified release	Attention deficit hyperactivity disorder and narcolepsy Attention deficit hyperactivity disorder	Tablet
	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 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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Therapeutic area	Product	Common name	Indication[1]	Formulation
Specialty Care				
Opthalmology	*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 (MS) 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 soft tissue infections (cSSTI) Right-sided endocarditis (RIE) due to Staphylococcus aureus Staphylococcus aureus bacteremia when associated with RIE or cSSTI	Powder for solution, injection or infusion
	Ilaris	canakinumab	Cryopyrin-associated periodic syndrome (CAPS)	Lyophilized powder for reconstitution for subcutaneous injection
	Myfortic	mycophenolic acid/mycophenolate sodium, USP	Prevention of graft rejection following kidney transplantation	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
	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 and kidney)	Tablet Dispersible tablet for oral suspension
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.

Selected Leading Products

Oncology

Gleevec/Glivec (imatinib mesylate tablets/imatinib) is a signal transduction inhibitor approved to treat patients with certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). First launched in 2001, *Gleevec/Glivec* is available in more than 110 countries. *Gleevec/Glivec* is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of CML.

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Gleevec/Glivec is also approved in the US, EU and Japan to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia, a rapidly progressive form of leukemia; and 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/Glivec* is also approved for aggressive systemic mastocytosis. *Gleevec/Glivec* has received approvals as a post-surgery (adjuvant setting) therapy for KIT+ GIST in more than 60 countries, including the US and EU. The CHMP also adopted a positive opinion in January 2012 recommending that the *Glivec* label be updated to include three years of adjuvant treatment for patients with resected KIT+ GIST. The FDA also granted a priority review of these data for the label.

Tasigna (nilotinib) is a signal transduction inhibitor of the tyrosine kinase activity of Bcr-Abl, KIT+ and the PDGF-receptor. Since 2007, *Tasigna* has gained regulatory approval in more than 90 countries including the US, EU, Switzerland and Japan, to treat patients with a form of CML in chronic and/or accelerated phase patients resistant or intolerant to existing treatment including *Gleevec/Glivec*. 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. The ENESTnd 36-month follow-up confirmed that *Tasigna* continued to surpass *Gleevec/Glivec* in inducing a deeper and more durable cytogenetic and molecular response and showed a lower incidence in transformation to accelerated phase and blast crisis. Results from ENESTcmr, the first randomized trial in patients with Ph+ CML to investigate the impact of switching adult patients with residual disease after a minimum of two years of treatment with *Gleevec/Glivec* to *Tasigna,* showed that 23% of the patients switched to *Tasigna* achieved undectable levels of Bcr-Abl within 12 months compared to 11% who continued on *Gleevec/Glivec.* The study showed a two-fold difference in confirmed undetectable CML for patients on *Tasigna* versus patients on *Gleevec/Glivec* although statistical significance was not achieved. *Tasigna* is now approved in 50 markets including the US, EU, Japan, and Switzerland for the treatment of adult patients with a form of newly diagnosed CML. The clinical trial ENESTg1 comparing *Tasigna* to *Gleevec/Glivec* in newly diagnosed patients with unresectable and/or metastatic gastrointestinal stromal tumors was discontinued following the recommendation of an independent data monitoring committee. Interim efficacy results indicated that *Tasigna* was unlikely to show superiority. A trial is 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 (SREs), 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), *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. A new ready-to-use (RTU) formulation of *Zometa* was approved by the FDA in June 2011 and launched in September 2011, offering improved convenience of use. The EMA approved this formulation in August 2011 and the product was launched in October in countries including Germany, Austria, UK, Ireland, Sweden, Denmark, Norway, Finland, Netherlands, Portugal, and Slovenia. Zoledronic acid, the active ingredient in *Zometa*, is also available under the trade names *Reclast/Aclasta* for use in non-oncology indications. *Zometa* and *Reclast/Aclasta* face significant competition from denosumab, a new Amgen product approved for the treatment of postmenopausal osteoporosis and cancer treatment-induced bone loss in the oncology setting, for SRE reduction or delay in patients with advanced malignancy involving bone. Denosumab is not approved in the multiple myeloma setting.

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 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* faced generic challenges in 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*.

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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 25 countries for the delay of tumor progression in patients with midgut carcinoid tumors. *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 who have a wide range of underlying anemias. 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 and Japan.

Afinitor/Votubia (everolimus), an oral inhibitor of the mTOR pathway, *Afinitor* is approved in more than 80 countries and regions including the US, EU and Japan for advanced renal cell carcinoma following vascular endothelial growth factor-targeted therapy. *Afinitor* was approved in May 2011 in the US, in September 2011 in the EU, and in December 2011 in Japan for the treatment of advanced progressive neuroendocrine tumors of pancreatic origin. Everolimus is also approved in 40 countries including in the US as *Afinitor* and 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. Additional Phase III data examining this patient population, EXIST-1, met its primary endpoint of SEGA response rate and supports these regulatory approvals. 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.

Primary Care

Primary Care

Arcapta Neohaler/Onbrez Breezhaler (indacaterol) is a long-acting beta$_2$-agonist delivered 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). *Onbrez Breezhaler* was first approved in the EU in November 2009 at two dose strengths, 150 mcg and 300 mcg, once-daily and is now approved in more than 80 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 Germany, the reimbursed price of *Onbrez Breezhaler* was reduced below that of generic LABAs from October 1, 2011, following a reference pricing review. We will maintain current prices in Germany, as we remain convinced that once-daily *Onbrez Breezhaler* offers additional benefits over existing LABAs, as described in the EU-approved label. Consequently an additional co-payment for *Onbrez Breezhaler* will be required for many patients in Germany.

Diovan (valsartan), together with *Diovan HCT/Co-Diovan* (valsartan and hydrochlorothiazide), is the world's number one selling high blood pressure medication (IMS August 2011; 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 16 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 European Union (EU) member states locally approved *Diovan* for use in children aged 6 to 18 years. *Diovan* faced generic challenges in 2011 when the patent on its active ingredient, valsartan, expired in the major countries of the EU, with patent expirations in the US and

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Japan to follow in 2012 and 2013 respectively. 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 angiotensin receptor blocker *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 80 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), CCB (amlodipine) and diuretic HCT (hydrochlorothiazide). *Exforge HCT* was approved in the EU and the US in 2009, and is now available in more than 40 countries.

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. The first single-pill combination product, *Tekturna/Rasilez* with hydrochlorothiazide was approved by the US in 2008 as *Tekturna HCT*, and in the EU in 2009, where it is known as *Rasilez HCT*. A second single-pill combination product, *Tekturna/Rasilez* with valsartan, called *Valturna* in the US, was launched in the US in 2009. The single-pill combination of *Tekturna/Rasilez* with the calcium channel blocker amlodipine besylate, known as *Tekamlo* in the US and *Rasilamlo* in the EU, was approved by the FDA in August 2010 and launched in January 2011. It was approved by the European Commission in April 2011. The single-pill triple combination of *Tekturna/Rasilez* with amlodipine besylate and hydrochlorothiazide was approved in the US in December 2010 and launched in January 2011 under the product name *Amturnide*. Under the tradename *Rasitrio*, the triple combination was approved in the EU in November 2011. In December 2011, 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 (DMC) overseeing the trial, after a higher risk of adverse events was identified in patients receiving *Tekturna/Rasilez* than those on placebo. Following discussions with health authorities, Novartis has written to healthcare professionals worldwide recommending that hypertensive patients with diabetes should not be given *Tekturna/Rasilez*-based products in combination with an ACE inhibitor or ARB, and that *Valturna* should not be given to diabetic patients. As an additional precautionary measure, Novartis has ceased promotion of *Tekturna/Rasilez*-based products for use in combination with an ACE or ARB. These products remain available for appropriate patients.

Galvus (vildagliptin), an oral treatment for type 2 diabetes, and *Eucreas*, a single-pill combination of vildagliptin and metformin, have shown promising results during the rollout in Europe following approvals in 2007. *Galvus* is currently approved in 89 countries and has been launched in 68. *Galvus* was most recently approved in China in August 2011. *Eucreas* was the first single-pill combining a DPP-4 inhibitor and another medication to be launched in Europe. *Eucreas* is currently approved in 79 countries and has been launched in 56 countries.

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 90 countries including the US, EU 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. *Zometa* and *Reclast/Aclasta* face significant competition from denosumab, a new Amgen product approved for the treatment of postmenopausal

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osteoporosis and cancer treatment-induced bone loss in the oncology setting, for SRE reduction or delay in patients with advanced malignancy involving bone.

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 pediatric and adult narcolepsy. *Ritalin* was first marketed during the 1950s and is available in over 50 countries. *Ritalin LA* is available in over 20 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* is available in the US. Immediate-release *Focalin* is subject to generic competition.

Specialty Care

Ophthalmology

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors. *Lucentis* is the first approved drug for wet age-related macular degeneration that has been shown to improve vision and vision-related quality of life. *Lucentis* was approved in the EU in 2007. It is now approved in more than 100 countries. In January 2011, the European Commission granted Novartis a new indication for *Lucentis* for the treatment of visual impairment due to diabetic macular edema, and since August 2010 it has been filed for this same indication elsewhere around the world, outside of the US. In May 2011, the European Commission approved a new indication for *Lucentis* for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion. *Lucentis* is developed in collaboration with Genentech, which holds the rights to market the product in the US.

Neuroscience

Gilenya (fingolimod) is the first in a new class of multiple sclerosis (MS) therapy called sphingosine 1-phosphate receptor modulators. *Gilenya* is the first approved oral disease-modifying treatment for MS in the US, a major advance for people with relapsing MS, the most common forms of the disease. *Gilenya* showed superior efficacy by reducing relapses by 52% at one year ($p < .001$) compared to interferon beta-1a IM, a current standard of care. A two-year, placebo-controlled study showed that *Gilenya* significantly reduced the risk of disability progression. *Gilenya* has a well-studied safety and tolerability profile with over 2,600 MS clinical trial patients included in the FDA regulatory review, with some patients in their seventh year of treatment. *Gilenya* is approved as a first line treatment for relapsing forms of MS in the US. In the EU, *Gilenya* was approved 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. *Gilenya* is currently approved in over 55 countries around the world. In September 2011, *Gilenya* received regulatory approval in Japan for the prevention of relapse and delay of progression of physical disability in adults with MS. *Gilenya* is licensed from Mitsubishi Tanabe Pharma Corporation. Novartis is working with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) on their reviews of the benefits and risks of *Gilenya* that were initiated following the report of a patient death that occurred within 24 hours after receiving the first dose of *Gilenya* in November 2011. The FDA has stated that, at this time, it cannot conclude whether the drug resulted in the November 2011 patient death. According to the EMA, the cause of that patient death is still unexplained. In addition the EMA described 10 other deaths as being of potential interest but noted that the role of *Gilenya* in these deaths has not been established. These other events preceded the

November 2011 death, and were reported to the health authorities per regulations. During the EMA review process and following the recent consultation with the EU Committee for Medicinal Products for Human Use (CHMP), Novartis is in the process of notifying physicians of new interim recommendations regarding the initiation of treatment with *Gilenya* in the European Union to be effective immediately. This includes the addition of continuous electrocardiogram (ECG) monitoring during the six-hour observation period

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following the first dose. First dose monitoring is already recommended in the *Gilenya* label. In patients who meet certain specified criteria, monitoring should be extended.

Exelon (rivastigmine tartrate) and *Exelon Patch* (rivastigmine transdermal system): *Exelon* capsules have been available since 1997 to treat mild to moderate Alzheimer's disease (AD) dementia in more than 90 countries. In 2006, *Exelon* became the only cholinesterase inhibitor to be approved for mild to moderate Parkinson's disease 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 launched in more than 60 countries. 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.

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 20 markets, 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. *Stalevo* and *Comtan* were developed and are manufactured by Orion, and are marketed by Novartis and Orion in their respective territories.

Integrated Hospital Care

Zortress/Certican (everolimus) is an mTOR inhibitor with immunosuppressant and anti-proliferative properties indicated for the prevention of transplant rejection in combination with basiliximab and concurrently with reduced doses of cyclosporine and corticosteroids. It has been sold as *Zortress* in the US since April 2010 and as *Certican* in the rest of the world since 2003. It is approved in the US for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal transplant, and launched in more than 85 countries for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal or cardiac transplant. Everolimus, the active ingredient in *Zortress/Certican*, is also available under the trade names *Afinitor* and *Votubia* for certain other indications, and is 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 50 countries for the treatment of children and adults 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.

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 allergic asthma in the US in adolescents (aged 12 and above) and adults. It is approved for severe allergic asthma in the EU in children (aged six and above), adolescents, and adults. *Xolair* is approved in more than 85 countries, including the US in 2003 and the EU in 2005. Following approval in the EU, a liquid formulation of *Xolair* in pre-filled syringes has been launched in most European countries. *Xolair* is being jointly developed with Genentech and is co-promoted in the US by Novartis and Genentech.

Tobi Podhaler (tobramycin inhalation powder) was approved in the EU in July 2011 as a suppressive therapy for chronic Pseudomonas aeruginosa lung infections in patients with cystic fibrosis aged six years and older. *Tobi Podhaler* is a new dry powder formulation of the antibiotic tobramycin, delivered using a more convenient, patient-friendly device that reduces administration time by 72% relative to *Tobi* (nebulizer solution), with comparable efficacy.

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.

Novartis, while essentially using the same model as a platform, has tailored the process to be simpler, more flexible and efficient. Our development paradigm consists of two parts: Exploratory 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.

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	Therapeutic area	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
ACZ885	canakinumab		Gouty arthritis				

Anti IL-1β monoclonal antibody		Integrated Hospital Care	Subcutaneous injection	EU: 2010 US: 2011	EU (registration) US (registration/
	Systemic onset juvenile idiopathic arthritis	Integrated Hospital Care		2009	2012/III
	Diabetes mellitus	Critical Care		2009	≥ 2016/II
	Secondary prevention of cardiovascular events	Critical Care		2011	≥ 2016/III

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Project/ Product	Common name	Mechanism of action	Potential indication/ Disease area	Therapeutic area	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
AEB071	sotrastaurin	Protein kinase C inhibitor	Prevention of organ rejection after transplantation kidney and liver	Integrated Hospital Care	Oral	2006	≥ 2016/II
			Psoriasis	Integrated Hospital Care		2009	≥ 2016/II
AFQ056	mavoglurant	Metabotropic glutamate receptor 5 antagonist	Fragile X syndrome	Neuroscience	Oral	2010	2013/II
			L-dopa induced dyskinesia in Parkinson's disease			2006	2014/II
AIN457	secukinumab	Anti IL-17 monoclonal antibody	Psoriasis	Integrated Hospital Care	Lyophilized powder in vial; Intravenous infusion, subcutaneous injection	2011	2013/III
			Arthritidies (Rheumatoid arthritis, Ankylosing Spondylitis, Psoriatic Arthritis)			2011	2013/III
			Multiple sclerosis	Neuroscience		2009	≥2016/II
ATI355	TBD	Anti NOGO-A mAb	Spinal cord injury	Neuroscience	Intrathecal spinal injection	2006	≥2016/I
AUY922	TBD	ATP-competitive nongeldanamycin inhibitor of HSP90	Solid tumors	Oncology	Intravenous	2010	≥2016/II
BAF312	TBD	Sphingosine-1-phosphate (S1P) receptor modulator	Multiple sclerosis	Neuroscience	Tablet	2009	≥2016/II
BCT197	TBD	Anti-inflammatory agent	Chronic obstructive pulmonary disease	Primary Care	Oral	2011	≥2016/II
BEZ235	TBD	P13K/mTOR inhibitor	Solid tumors	Oncology	Oral	2011	2014/II
BGS649	TBD	Aromatase inhibitor	Obese hypogonadotropic hypogonadism	Critical care	Oral	2010	≥2016/II
BKM120	TBD	P13K inhibitor	Endometrial cancer	Oncology	Oral	2011	2014/II
CAD106	TBD	Beta-amyloid-protein immunotherapy	Alzheimer's disease	Neuroscience	Subcutaneous, intramuscular injection	2008	≥2016/II
DEB025	alisporivir	Cyclophilin inhibitor	Chronic hepatitis C	Integrated Hospital Care	Oral	2011	2013/III

Exjade	deferasirox	Iron chelator	Non-transfusion dependent thalassemia	Oncology	Oral	2011	EU (registration) US (registration)
Gilenya	fingolimod	Sphingosine-1-phosphate (S1P) receptor modulator	Chronic inflammatory demyelinating poly-radiculoneuropathy	Neuroscience	Oral	2012	2014/II
HCD122	TBD	Anti-CD40 monoclonal antibody	Hematological tumors	Oncology	Intravenous	2011	2016/II
INC424	ruxolitinib	Janus kinase (JAK) inhibitor	Myelofibrosis	Oncology	Oral	2011	EU (registration)
			Polycythemia vera			2010	2014/III (outside US)
LBH589	panobinostat	Histone deactelylase inhibitor	Relapsed or relapsed-and-refractory Multiple Myeloma	Oncology	Oral	2009	2013/III
			Hematological cancers			2009	≥ 2016/II
LCI699	TBD	Aldosterone synthase inhibitor	Solid tumors	Oncology	Oral	2011	≥ 2016/II

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Project/ Product	Common name	Mechanism of action	Potential indication/ Disease area	Therapeutic area	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
LCQ908	TBD	Diacylglycerol acyl transferase-1 inhibitor	Metabolic diseases	Critical Care	Tablet	2010	2014/II
LCZ696	TBD	Angiotensin receptor-Neprilysin Inhibitor	Heart failure	Critical Care	Oral	2009	2014/III
			Hypertension	Primary Care		2007	2014/II
LDE225	TBD	Oral smoothed inhibitor	Gorlin Syndrome Advanced basal cell carcinoma	Oncology	Oral	2011	2014/II
LFF571	TBD	Bacterial elongation factor Tu (EFTu) inhibitor	Clostridium difficile infection	Integrated Hospital Care	Oral	2010	≥2016/II
LGT209	TBD	Lipid modulator	Hypercholesterolemia	Critical Care	Oral	2011	≥2016/II
Lucentis	ranibizumab	Anti-VEGF monoclonal antibody fragment	Pathological myopia	Ophthalmology	Intravitreal injection	2010	2012/III
		Choroidal neovascularization and Macular edema	Ophthalmology			2010	≥2016/II
MEK162	TBD	MEK inhibitor	Solid tumors	Oncology	Oral	2011	≥2016/II
NIC002	TBD	Nicotine Qbeta therapeutic vaccine	Smoking cessation	Primary Care	Injection	2008	≥ 2016/II
NVA237	glycopyrronium bromide	Long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Primary Care	Inhalation	EU: 2011	EU (registration) US (TBD)
PKC412	midostaurin	Signal transduction inhibitor	Aggressive systemic mastocytosis	Oncology	Oral	2005	2013/II
			Acute myeloid leukemia			2008	2014/III
QAW039	TBD	Anti-inflammatory agent	Asthma	Primary Care	Oral	2010	≥2016/II
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
QTI571	imatinib mesylate	Protein tyrosine kinase inhibitor	Pulmonary arterial hypertension	Critical Care	Oral	2009	2012/III

QVA149	indacaterol and glycopyrronium bromide	Long-acting beta2-agonist and long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Primary Care	Inhalation	2010	2012/III
RAD001 (*Afinitor)*	everolimus	mTOR inhibitor	Tuberous sclerosis complex-Angiomyolipoma	Oncology	Tablet	2011	US (registration) EU (registration)
			Advanced ER+HER2- breast cancer			2011	US (registration) EU (registration)
			Breast cancer HER2-over-expressing, 1st line			2009	2013/III
			Breast HER2-over-expressing 2nd/3rd line			2009	2013/III
			Hepatocellular carcinoma			2010	2013/III
			Lymphoma			2009	2015/III
RLX030	TBD	Vascular modulator	Acute heart failure	Critical Care	Intravenous infusion	2009	2013/III

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Project/ Product	**Common name**	**Mechanism of action**	**Potential indication/ Disease area**	**Therapeutic area**	**Formulation/ Route of administration**	**Year Project Entered Current Development Phase**	**Planned filing dates/Current phase**
SOM230	pasireotide	Somatostatin analogue	Cushing's disease	Oncology	Immediate release: subcutaneous injection	EU:2010 US:2011	EU (registration), US (2012/III)
			Acromagaly		Long-acting release: monthly intramuscular injection	2008	2012/III
			Carcinoid syndrome		Long-acting release: monthly intramuscular injection	2008	2013/III
Tasigna	nilotinib	Signal transduction inhibitor	metastatic melanoma with c-KIT mutation	Oncology	Capsule	2011	2014/II
Tobi Podhaler	tobramycin inhalation powder	Aminoglycoside antibiotic	Pseudomonas aeruginosa infection in cystic fibrosis patients	Critical Care	Dry powder inhalation	EU: 2011 US: 2010	EU (approved) US (2012/III)
Tekturna ATMOSPHERE	aliskiren	Direct renin inhibitor	Reduction of CV death/hospitalizations in chronic heart failure	Critical Care	Tablet	2009	2014/III
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	Critical Care	Lyophilized powder for reconstitution as subcutaneous injection	2011	2013/III
Zortress/Certican	everolimus	mTOR inhibitor	Prevention of organ rejection liver	Integrated Hospital Care	Oral	EU: 2011 US: 2011	EU (registration) US (registration)

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 February 2011 for the treatment of acute attacks in gouty arthritis (GA). The Phase III program in GA showed superior pain relief and a much reduced risk of new attacks compared to an injectable corticosteroid. An FDA Advisory Committee Meeting in June 2011 voted in favor of the overall efficacy, but recommended that additional retreatment data would be needed to assess the overall safety profile of ACZ885 in the treatment of GA. A Complete Response letter was received in August 2011 from the FDA with a request for additional information, including clinical data to evaluate the benefit risk profile in refractory patients. Novartis is currently working with the FDA to determine the next steps for ACZ885 in gouty arthritis. In Europe, the outcome of the EU response

regarding GA is expected in the first half of 2012. In systemic juvenile idiopathic arthritis (SJIA), results from two pivotal Phase III trials showed ACZ885 provided significant symptom relief and helped to substantially reduce oral steroid use in SJIA patients. Worldwide regulatory submissions are planned for 2012. ACZ885 is also being investigated for the secondary prevention of cardiovascular events and for the treatment of Diabetes Mellitus.

AEB071 (sotrastaurin) is a low molecular weight, selective inhibitor of protein kinase-C (PKC). Inhibition of PKC reduces T-cell activation through a novel calcineurin-independent pathway. The molecule is in Phase II clinical development for the treatment of autoimmune indications (including psoriasis) and for the prevention of solid organ allograft rejection (kidney and liver transplantation).

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AFQ056 (mavoglurant) is a metabotropic glutamate receptor 5 (mGluR5) antagonist in Phase II 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 human monoclonal antibody neutralizing interleukin-17A, a key pro-inflammatory cytokine expressed by TH17 cells and other types of white blood cells. The compound is in Phase III development in psoriasis and arthritidies (rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis), where initial studies suggested that AIN457 may provide a new mechanism of action for the treatment of immune-mediated diseases.

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 is expected to enter Phase III development in 2012.

DEB025 (alisporivir) is a cyclophilin inhibitor for the treatment of Hepatitis C virus infection (HCV). DEB025 was in-licensed from Debiopharm in early 2010. Phase III studies in HCV genotype 1 treatment-naïve are ongoing as well as a Phase IIb study in treatment-experienced patients and a Phase IIb study in patients with HCV genotype 2 and genotype 3, assessing the potential of DEB025 as an interferon-free therapy for this population.

Gilenya (fingolimod) was approved in the US in September 2010 as a first line treatment for relapsing forms of MS and in the EU in March 2011 as a disease modifying therapy in patients with highly active RRMS despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS. A pediatric study in MS as well as a Phase II/III study in patients with chronic inflammatory demyelinating polyradiculoneuropathy are planned to be 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 study (2209), the first prospective controlled study of iron chelation in NTDT patients, met the primary endpoint by demonstrating a significant decrease in iron burden in both the *Exjade* 5 and 10 mg arms compared to placebo. Regulatory filings were submitted in the EU and US in December 2011 for use of *Exjade* in patients with non-transfusion-dependent thalassemia.

INC424 (ruxolitinib) is an investigational Janus kinase (JAK) inhibitor. This oral targeted therapy has completed Phase III clinical trials for the treatment of myelofibrosis, a life-threatening blood cancer. It is characterized by bone marrow failure, splenomegaly (enlarged spleen) and debilitating symptoms, including fatigue and pain. Novartis has licensed the rights to INC424 from Incyte for development and potential commercialization outside the US. In the third quarter of 2011, a marketing authorization was submitted to the EMA for the treatment of myelofibrosis based on the results of two Phase III clinical trials, COMFORT-I and COMFORT-II. Positive results from both Phase III trials presented in 2011 demonstrated that INC424 significantly reduced disease burden when compared to either placebo or the best available therapy. Additionally, INC424 provided clinically relevant and statistically significant improvements in symptoms at each evaluation when compared to best available therapy. An early analysis of COMFORT-I data shows INC424 treatment resulted in greater overall survival advantage when compared to placebo. INC424 is also being investigated in Polycythemia Vera. The pivotal Phase III RESPONSE trial is currently enrolling patients to study INC424 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 in the rest of the world.

LBH589 (panobinostat) is a highly potent pan deacetylase inhibitor targeting the epigenetic regulation of multiple oncogenic pathways, with development focused on hematological disease. In January 2011 the FDA issued a Refusal to File letter regarding the new drug application for LBH589 for the treatment of patients with relapsed/refractory Hodgkin lymphoma. LBH589 continues in Phase III development in the

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ongoing PANORAMA-1 Phase III trial of bortezomib/dexamethasone plus panobinostat or placebo in relapsed or relapsed-and-refractory multiple myeloma. We plan to file LBH589 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 II development for the treatment of metabolic disorders.

LCZ696 is a first-in-class angiotensin receptor 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 study PARADIGM-HF tests the efficacy and safety of LCZ696 compared with the ACE inhibitor enalapril on morbidity and mortality or heart failure hospitalizations. LCZ696 is also in Phase II development for the treatment of hypertension.

Lucentis (ranibizumab) was approved in the EU in January 2011 for the treatment of visual impairment secondary to diabetic macular edema and in May 2011 for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion. A Phase III program for the Pathologic myopia indication was initiated with first patient visit in October 2010.

NVA237 (glycopyrronium bromide), a long-acting muscarinic antagonist (LAMA), is being developed as a once-daily treatment for chronic obstructive pulmonary disease (COPD) in a single-dose dry-powder inhaler. Phase III trials have shown that NVA237 50 mcg once-daily had superior efficacy and comparable safety to placebo. In an exploratory arm, NVA237 produced similar improvements in lung function (measured by trough FEV_1 at 12 weeks) to open-label tiotropium, the only once-daily LAMA presently on the market. The first regulatory submission was made in the EU in the third quarter of 2011 with the proposed brand-name *Seebri Breezhaler*. In the US, NVA237 will require additional clinical data to support submission and thus will be delayed.

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). Filing is expected for ASM with Phase II data in 2013 and for newly diagnosed, FLT3-mutated AML with Phase III data by 2014.

QMF149 is an investigational once-daily fixed-dose combination of the long-acting $beta_2$-agonist QAB149 (indacaterol) and the inhaled corticosteroid mometasone, licensed from Merck (formerly Schering-Plough), 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. Activities directly related to US development are not currently planned to be initiated.

QVA149 is an investigational fixed-dose combination of the long-acting $beta_2$-agonist QAB149 (indacaterol) and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide), being developed as a once-daily treatment for COPD, in a single-dose dry-powder inhaler. Phase II studies have been successfully completed and results demonstrated that the fixed-dose combination QVA149 provided superior bronchodilation compared to QAB149 or placebo, which was sustained over 24 hours. The compound had a fast onset of action at first dose and was well tolerated with a good overall safety profile comparable to placebo. Phase III development is on track for 2012 submission in the EU and other countries outside the US. As a result of the NVA237 delay in the US, the QVA149 submission is delayed in the US.

QTI571 (imatinib mesylate tablets/imatinib), an inhibitor of tyrosine kinase activity, is currently in development for pulmonary arterial hypertension (PAH). PAH is a rare, progressive, proliferative disease with high morbidity and mortality. A Phase III program in severe PAH patients has completed. The study met its primary endpoint of improvement in six-minute walk distance and there were significant improvements in key haemodynamic measurements compared to placebo. QTI571 did not improve time to clinical worsening. Safety was as expected for imatinib. The first regulatory submissions are expectedin the first quarter of 2012. Imatinib is the active ingredient in *Gleevec/Glivec.*

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 tuberous sclerosis complex (TSC). Results of the Phase III BOLERO-2 (Breast cancer trials of OraL EveROlimus-2) study showed everolimus combined with hormonal therapy more than doubled time women lived without tumor growth

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and significantly reduced the risk of cancer progression versus hormonal therapy alone in women with postmenopausal ER+HER2- advanced breast cancer. Worldwide filings were submitted at the end of 2011 based on these data. Everolimus is also being investigated for the treatment of ER+HER2+ advanced breast cancer in two Phase III pivotal studies. In addition, a Phase III data set in patients with angiomyolipomas associated with TSC met its primary endpoint of best overall angiomyolipoma response rate, and served as the base for worldwide filings (US file submitted in the fourth quarter of 2011; EU file submitted in January 2012), for a second TSC indication for everolimus. The Phase III GRANITE-1 (Gastric Antitumor Trial with Everolimus) trial in patients with advanced gastric cancer has been completed and the study did not meet the primary endpoint of extending overall survival.

RLX030 is a recombinant form of human relaxin-2, which was obtained by Novartis through the acquisition of Corthera, Inc. in February 2010. RLX030 is being developed for patients hospitalized for acute heart failure. The Phase II data in this population indicated rapid and sustained symptom relief along with an outcome benefit, following a continuous intravenous infusion, on top of standard of care. The ongoing Phase III development program is investigating the short- and long-term efficacy and safety of RLX030.

SOM230 (pasireotide) is a somatostatin analogue in development for patients with Cushing's disease, acromegaly and refractory/resistant carcinoid syndrome. Data from a pivotal study in Cushing's disease showing significant reduction of cortisol secretions are the basis for regulatory submissions of the SOM230 subcutaneous formulation. In the third quarter of 2011, the FDA new drug application that had been submitted for SOM230 in June was withdrawn due to a technical issue identified in a routine analysis of batches of SOM230 s.c. formulation. Novartis plans to resubmit the application following further discussion with the FDA. In January 2012, the CHMP adopted a positive opinion for SOM230 for the treatment of patients with Cushing's disease. In the first quarter of 2011, a Phase III trial comparing SOM230 LAR against *Sandostatin LAR* met the primary endpoint of normalization of IGF-1 and growth hormone levels in the treatment of patients with acromegaly. A Phase III trial comparing SOM230 LAR against *Sandostatin LAR* in patients with carcinoid tumors refractory/resistant to somatostatin analogues is ongoing.

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

Tekturna/Rasilez (aliskiren) is a treatment for high blood pressure, and the first and only approved direct renin inhibitor. In December 2011, Novartis announced that following the seventh interim review of data from the ALTITUDE study, a decision to terminate the trial had been taken on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the trial. The DMC concluded that patients were unlikely to benefit from treatment added to standard anti-hypertensives, and identified higher adverse events in patients receiving Tekturna/Rasilez in addition to standard of care in the trial. The trial was investigating the potential reduction in risk of cardiovascular/renal events for diabetics with renal impairment with or without cardiovascular disease. In addition, *Tekturna/Rasilez* is the subject of the ongoing ATMOSPHERE trial, which is studying the potential reduction in risk of cardiovascular death/heart failure hospitalization in patients with chronic heart failure, and is expected to be submitted to health authorities in 2014.

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 is currently recruiting patients.

Xolair (omalizumab): Novartis and Genentech commenced development of omalizumab in a new indication, chronic idiopathic urticaria, and Phase III studies began in 2011.

Zortress/Certican (everolimus) is an mTOR inhibitor with immune/non-immune cell proliferation inhibition being developed for prevention of solid organ transplant rejection. In 2008, Phase III development was initiated worldwide for the prevention of organ rejection in liver transplantation. In 2009, Phase III development was initiated in the US for an expanded kidney transplant indication of *Zortress* in combination with tacrolimus and corticosteroids.

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Projects Added To And Subtracted From The Development Table Since 2010

Project/Product	Potential indication/ Disease area	Change	Reason
AGO178	Major depressive disorder	Terminated	Clinical results did not meet required standards
AIN457	Non-infectious uveitis	Transferred to Alcon Division	Project was transferred to Alcon Division together with other Novartis Ophthalmics assets after our merger with Alcon, Inc.
AUY922	Solid tumors	Project Added	Entered confirmatory development
BGS649	Refractory endometriosis	Terminated	Clinical results did not meet required standards
Elidel®	Atopic dermatitis in infants	Divested	Novartis sold global rights to third party
Gilenya	Multiple sclerosis	Commercialized	Received formal approval in EU and Japan in 2011
Joicela	Osteoarthritis	Terminated	Novartis withdrew its European application for *Joicela* (lumiraxcoxib) in combination with a genetic biomarker test. The decision was based on the inability to provide additional requested data within the timeframe of the current procedure. We remain committed to personalized medicines and biomarker testing programs. Currently lumiracoxib is not under review by any health authorities and there are no plans to submit in the near term.
LBH589	Hodgkin's Lymphoma	Terminated	Received Refusal to File letter from FDA
LGT209	Hypercholesterolemia	Project added	Entered confirmatory development
Lucentis	Retinal vein occlusion	Commercialized	Received marketing approval in EU in 2011
PRT128	Chronic coronary heart disease	Terminated	Clinical results did not meet required standards
PTK796	Acute bacterial skin and skin structure infections, community-acquired bacterial pneumonia	Terminated	Regulatory approval timing became uncertain. Collaboration terminated; all rights returned to Paratek.
QAB149 *(Arcapta Neohaler/Onbrez Breezhaler)*	Chronic obstructive pulmonary disease	Commercialized	Received marketing approval in US and Japan
QAW039	Asthma	Project added	Entered confirmatory development
RAF265	Solid tumors	Project added	Entered confirmatory development
RAD001 (Afinitor)	Tuberous sclerosis complex- subependymal giant cell astrocytoma	Commercialized	Received marketing approval in EU
RAD001 *(Afinitor)*	Neuroendocrine tumors	Commercialized	Received marketing approval in US and EU

RAD001 *(Afinitor)*	Advanced gastric cancer	Terminated	Clinical results did not meet required standards
Tasigna	First line metastatic gastrointestinal stromal tumors	Terminated	Clinical results did not meet required standards
Tekamlo/Rasilamlo single pill combination	Hypertension	Commercialized	Received marketing approval in EU

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Project/Product	Potential indication/ Disease area	Change	Reason
Tekturna/Rasilez single-pill combination (three active ingredients)	Hypertension	Commercialized	Received marketing approval in EU

Principal Markets

The Pharmaceuticals Division has a commercial presence in approximately 140 countries worldwide, but net sales are generally concentrated in the US, Europe and Japan, which together accounted for 78.4% of 2011 of the division's net sales. At the same time, sales from fast growing "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	2011 Net sales to third parties	
	$ millions	%
United States	9,973	30.7
Americas (except the United States)	3,012	9.3
Europe	11,595	35.7
Japan	3,909	12.0
Rest of the World	4,019	12.3
Total	**32,508**	**100**

Many of our Pharmaceuticals Division's products are used for chronic conditions that require patients to consume the product over long periods of time, 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 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

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supply of essential materials. Our suppliers of raw materials are required to comply with Novartis quality standards.

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.

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 approximately 3,600 field force representatives in the US (including supervisors), and an additional 18,937 in the rest of the world, as of December 31, 2011. 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 is expected to result 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 as well as economically attractive.

The marketplace for healthcare is evolving with the consumer becoming a more influential 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 with substantial financial and other resources, which sell patented prescription pharmaceutical products. 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 remedies 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.

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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:

	2011		2010[1]		2009[1]	
	$ billion	$ billion, excluding impairment and amortization charges	$ billion	$ billion, excluding impairment and amortization charges	$ billion	$ billion, excluding impairment and amortization charges
Research and Exploratory Development	2.7	2.6	2.4	2.3	2.2	2.1
Confirmatory Development	4.5	4.3	4.9	4.0	3.8	3.8
Total	**7.2**	**6.9**	**7.3**	**6.3**	**6.0**	**5.9**

(1) Restated to account for the transfer of Corporate Research to the Pharmaceuticals Division

The $7.2 billion (6.9 billion excluding impairment and amortization charges) that the Pharmaceuticals Division invested in research and development in 2011 represented 22.1% (21.1% excluding impairment and amortization charges) of the division's total net sales. The Pharmaceuticals Division currently has 130 projects in clinical development.

Innovation is critical to long-term success in the pharmaceutical industry. In 2010, the industry's average spend of pharmaceutical companies on research and development activities was 15% of net sales, but that number is declining as some companies increasingly 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 plan to continue to do so. Our Pharmaceuticals Division research and development investment in excess of 20% of the division's net sales in both 2011 and 2010 reflects this.

Research and Exploratory Development grew at constant currencies by $109 million (4.6%) in 2011 over 2010. The additional cost reflects our investment in scientific talent. At period rates, the currency impact added an additional $200 million, bringing total growth to $309 million (13%), increasing the amount invested in Research and Exploratory Development from $2.4 to $2.7 billion.

Confirmatory Development expenditure in 2011 decreased by 7% to $4.5 billion. This included $0.3 billion in impairments of intangible assets primarily related to the discontinuation of PTK796, PRT128, and AGO178. In 2010, impairments of intangible assets were $0.9 billion. Excluding impairments, Confirmatory Development expenditure increased 7% to $4.3 billion in 2011 and represented 13.1% of net sales in 2011 compared to 13.2% in 2010.

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 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.

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Research program

Our Research program is responsible for the discovery of new medicines. In 2003, we established the Novartis Institutes for BioMedical Research (NIBR).

At NIBR's headquarters in Cambridge, Massachusetts, more than 1,850 scientists and associates conduct research into disease areas such as cardiovascular and metabolism disease, infectious disease, oncology, muscle disorders and ophthalmology. An additional 4,500 scientists and technology experts conduct research in Switzerland, UK, Italy, Singapore, China and four 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 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.

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.

Our principal goal is to discover new medicines for diseases with high 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 dramatically 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.

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

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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.

Novartis Molecular Diagnostics

Recent advances in biology and bioinformatics have led to a much deeper understanding of the genetic underpinnings of disease and drug targets. Novartis Molecular Diagnostics (MDx), an integrated unit within our Pharmaceuticals Division, 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.

At its core, Novartis MDx is rooted in our leadership in drug discovery and development, and advancing "personalized medicine" is a key component of our overall strategy. Working closely with, and building on the strong science of NIBR and our Pharmaceuticals Division, MDx works to bring the full power of our internal capabilities and resources to bear in an effort to develop and commercialize important new diagnostic tests to support our development products and disease areas. Additionally, MDx strategically works with external collaborators to leverage technologies and capabilities that fit our diagnostic requirements.

In early 2011, Novartis MDx expanded its offerings through the acquisition of Genoptix Medical Laboratory, located in Carlsbad, California. With this new asset, Novartis MDx provides comprehensive laboratory services to community-based hematologists and oncologists. Our aim is to improve health outcomes for patients by advancing the ability of physicians to define and monitor individualized treatment programs.

Novartis MDx 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. We have developed a robust and expanding portfolio of molecular diagnostic programs and aim for multiple launches over the next few years to expand on the current offerings provided through Genoptix.

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

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country while the registration authority in 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 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 or BLA or 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.

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

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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 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 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 remain in place 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.

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United States. In the US, as a result of health care reform legislation enacted in 2010 and the recent focus on deficit reduction, there is a significant risk of continued actions to control prices. Specifically, one of the proposals that was considered by the bipartisan Joint Select Committee on Deficit Reduction ("Super Committee") would have imposed 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 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, and new required discounts in the Medicare Part D program, 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. In addition, prices for marketed products are referenced within Member States and across Member State borders, including new EU Member States.

Japan. In Japan, the government generally introduces price cut rounds every other year, and the government additionally mandates price decreases for specific products. In 2010, 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 2010. 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 2012.

Rest of World. Many other countries around the world are also taking steps to rein in prescription drug prices. As just one example, in 2010, Turkey, one of our most important emerging growth markets, imposed a price reduction on prescription drugs ranging from 11-23%.

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

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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 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 United States, 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.

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.

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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 it 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 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 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 2014 in Japan. 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, where we do not have protection for the compound, we brought suit in 2007 for infringement of the imatinib formulation, indication and crystal form patents against a local company that had obtained generic marketing authorization for a generic version of *Glivec*. We obtained a preliminary injunction in Turkey, but it was lifted in 2008. Litigation is ongoing. In Canada, two generic companies have challenged the compound patent.

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

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Zometa and *Reclast/Aclasta.* Patent protection on zoledronic acid, the active ingredient in these products, will expire in 2013 in the US and 2012-2013 in other major markets. We have settled patent litigation which we brought in the US against a generic manufacturer who challenged our patent on zoledronic acid. Under the settlement agreement, the generic manufacturer has dropped the challenge against the Novartis patent and will not launch zoledronic acid in the US until after the patent covering *Zometa* and *Reclast* expires in March 2013. In Canada, a generic company has challenged the compound patent.

Femara. Patent protection for the active ingredient in *Femara* expired in 2011 in the US and in major European markets, and will expire 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.

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.

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. We have patent protection on valsartan, the active ingredient used in our best-selling products *Diovan* and *Co-Diovan*/*Diovan HCT*, until September 2012 in the US (including pediatric extension), and until 2013 for *Diovan* and 2016 for *Co-Diovan* in Japan (including patent term extensions). In the major countries of the EU, patent protection for *Diovan*, including patent term and pediatric extensions, expired in November 2011, with further patent term extensions for *Co-Diovan* granted until September 2012 in Italy, Belgium, Finland, Greece, Luxembourg, Norway, and the Netherlands. Patent litigations are ongoing against generic manufacturers in Europe and Asia.

Exforge. Exforge is a single-pill combination of amlodipine besylate and valsartan. The valsartan patents expire from 2011 to13 (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 in October 2014. 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.

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 2019-24.

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 manufactures remains ongoing in the US.

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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".

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 *Gilenya* until 2021, which could possibly be extended by one year. Patent protection for the commercial formulation of *Gilenya* will expire in 2024 in most major markets, including the EU and Japan. 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, will expire in 2012 in the US and expired 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 2012-14 in major markets. *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 September 2011, however, two other 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. In some European countries generic manufacturers have obtained marketing approvals for an oral *Exelon* formulation. In June 2010, several generic manufacturers in Spain were enjoined from selling generic versions of the oral formulation. In France, a generic manufacturer launched a generic oral formulation in July 2011 and Novartis sued for patent infringement. Challenges to the remaining patent covering the oral form in Europe (the patent on the specific isomeric form) are ongoing in several European countries.

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 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, will expire in the US in 2013 and in Europe in 2012. 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 may launch 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.

Stalevo. One of the active ingredients in *Stalevo* is entacapone, the active ingredient in *Comtan.* Patent protection for entacapone will expire in 2012-13 (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, allowing the generic challengers to launch generic versions of *Stalevo* in April 2012, prior to the expiration of the entacapone compound patent. Novartis was not a party to the litigation.

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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. One of the resulting patent litigations has been settled. Litigation against several other generic manufacturers is ongoing in the US.

Critical Care

Xolair. Patent protection for the active ingredient in *Xolair* will expire in 2018 in the US, in 2017 in Europe, and in 2012 in other markets.

Tobi Podhaler. There is no patent protection for the active ingredient tobramycin. Patents covering the commercial product will expire in 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 determined after the product is approved.

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:

INC424. Assuming approval in 2012, patent protection for INC424 would expire in 2027 in the EU. If INC424 is approved in years after 2012, it may be eligible for a Supplemental Patent Certification that may extend the patent term for a period of time which depends upon the year in which the product is approved and the impact of the overall cap on such extensions in the EU of 15 years from the approval date. US rights to INC424 are held by Incyte Corporation.

NVA237. There is no patent protection on the active ingredient in NVA237. A number of patents covering the formulations, commercial product and uses of this product would expire by 2025. In addition, we expect that this product would be entitled to regulatory exclusivity for the data generated for approval, for a period of 10 years from the date of approval in the EU; for 3 years from the date of approval in the US; and for 8 years from the date of approval in Japan.

SOM230. SOM230 is subject to patent protection in the US until 2026. In the EU, SOM230 is subject to patent protection until 2021, and is eligible for a Supplemental Patent Certification that may extend the patent term for a 5 year period from the date of approval.

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

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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, 2011, the Alcon Division employed 22,987 full-time equivalent associates worldwide in 75 countries. In 2011, the Alcon Division had consolidated net sales of $10.0 billion representing 17% 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 is now our fifth growth platform alongside innovative pharmaceuticals, generics, vaccines and diagnostics, and consumer health. The 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. Our Alcon Division has nearly 2,000 people dedicated to research and development. In addition, our Alcon Division will work together with the Novartis Institutes for BioMedical Research (NIBR), our global pharmaceutical research organization. This collaboration is expected to allow our Alcon Division to leverage the resources of NIBR in an effort to discover expanded 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.

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 for cataract procedures, the *Constellation* vision system for retinal operations, and the *AcrySof* family of intraocular lenses (IOLs), including the *AcrySof* IQ, *AcrySof* IQ *ReSTOR, AcrySof IQ Toric* and *AcrySof IQ ReSTOR Toric* IOLs. In 2011, our Alcon Division launched the *LenSx* femtosecond laser, an emerging technology in cataract surgery which increases the precision and reproductibility for corneal incisions, 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 diseases of the eye including glaucoma and allergies as well as anti-infective/anti-inflammatory and dry eye treatments. Our Alcon Division's Ophthalmic Pharmaceuticals business also oversees the line of professionally driven over-the-counter brands in artificial tears

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and ocular vitamins. Product highlights within our Alcon Division's Ophthalmic Pharmaceuticals portfolio include *Travatan Z* solution and *DuoTrav* solution for the treatment of elevated intraocular pressure associated with glaucoma; *Vigamox* solution for bacterial conjunctivitis; *Pataday* solution for ocular itching associated with allergic conjunctivitis; and *Nevanac* suspension for eye inflammation following cataract surgery.

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."

Vision Care

Our 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 Alcon's *Opti-Free* line of multi-purpose disinfecting solutions, and CIBA Vision's *Clear Care* and *AOSept Plus* hydrogen peroxide lens care solutions, as well as CIBA Vision's broad portfolio of silicone hydrogel, daily disposables and color contact lenses, offered respectively within the *Air Optix*, *Dailies* and *Freshlook* brands. Through the integration of CIBA Vision products, Alcon is now one of the largest manufacturers across contact lenses and lens care products.

Recently Launched Products

Alcon launched a number of significant products in 2011, including:

Dailies Total 1 lenses Water gradient daily disposable silicone hydrogel contact lenses launched in Benelux and Nordic countries in Europe. *Dailies Total 1* represents the first new contact lens brand launched under the new Alcon Division.

Opti-Free EverMoist Multi Purpose Disinfecting Solution launched in Europe and Australia. The same product was launched in the US as *Opti-Free PureMoist* Multi Purpose Disinfecting Solution.

LenSx laser femtosecond laser launched globally in more than 16 countries, providing surgeons an image-guided laser that predictably and precisely performs several of the most challenging aspects of cataract surgery to deliver consistent refractive outcomes.

AcrySof IQ ReSTOR Toric lens advanced technology intra-ocular lens (ATIOL) launched in countries that recognize the CE Mark. This lens combines the multifocal technology of the *AcrySof IQ ReSTOR* with the *AcrySof IQ Toric* IOL providing cataract patients an IOL that delivers quality vision at all distances and corrects their astigmatism.

AcrySof IQ Toric T6-T9 lens CE-marking and FDA approval of intraocular lens for correction of astigmatism in the 2D-4D range.

Travatan BAK-free solution further expands Alcon?s global benzalkonium chloride (BAK) free glaucoma product portfolio. The BAK-free version of *Travatan* is formulated with Polyquad, an anti-microbial preservative which has demonstrated to be safe and gentle to the ocular surface. *Travatan* BAK-free is now available in the EU, Australia, Malaysia, Korea, Pakistan, Taiwan, Singapore and Argentina.

DuoTrav BAK-free solution further expands Alcon's global benzalkonium chloride (BAK) free glaucoma product portfolio. The BAK-free version of *DuoTrav* is formulated with Polyquad, an anti-microbial preservative which has demonstrated to

be safe and gentle to the ocular surface. *DuoTrav* BAK-free was launched in the EU, Brazil, Venezuela, Argentina, Malaysia, Singapore and Korea.

Moxeza solution US approval for a new formulation using the active ingredient of *Vigamox*, for bacterial conjunctivitis.

Systane Balance eye drops US and EU approval of new lubricant eye drops for patients with dry eye associated with meibomian gland dysfunction.

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.

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Surgical

Alcon's Surgical portfolio includes cataract, vitreoretinal, refractive error and glaucoma equipment and devices. In 2011, Alcon achieved the number one selling position globally in intraocular lenses, cataract and vitreoretinal equipment and the number two selling position globally in refractive error equipment, according to Market Scope.

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
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 LASIK vision correction
	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.

Ophthalmic Pharmaceuticals

Alcon is number one in dollar market share globally with its allergy and ocular fluoroquinolone anti-infective products and the number two position globally for glaucoma treatments, according to IMS Health. In addition, Alcon offers the number one selling portfolio to treat ear infections, led by *Ciprodex* Otic Suspension, according to IMS Health.

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)
Anti-Infectives	*Vigamox* and *Moxeza* Ophthalmic Solution for treatment of bacterial conjunctivitis
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 that target ocular conditions for which a corticosteroid is indicated and a bacterial infection or risk of bacterial infection exists
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

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Allergy	*Patanol* and *Pataday* Ophthalmic Solutions for itching associated with allergic conjunctivitis
	Patanase nasal spray for seasonal nasal allergy symptoms
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

* CiproDex® is a registered trademark of Bayer, AG.

The addition of the Novartis ophthalmics product line, with the exception of *Lucentis*, further enhanced Alcon's Ophthalmic Pharmaceuticals product offerings. The Novartis ophthalmics brands transferred to Alcon, effective July 1, 2011 (not all products and indications are currently available in every country and are subject to local regulatory requirements and timing from a segment reporting perspective these products have been retroactively restated to the Alcon segment from January 1, 2009) were:

Glaucoma	*Nyogel* reduction of intraocular pressure
Anti-Infection	*Okacin* ophthalmic solution for treatment of bacterial conjunctivitis (Turkey only)
Anti-Inflammation	*Voltaren Ophtha* Treatment of postoperative inflammation after cataract surgery, temporary relief of pain and photophobia after refractive surgery
Dry Eye	Lubricants for eye dryness, discomfort or ocular fatigue:
	Genteal
	Viscotears
	Oculotect (outside US markets)
	Hypotears
Ocular Allergy	*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)
Other Products	*Lid-Care* lid cleansing solution
	Vitalux nutrient supplements help patients with age-related macular degeneration maintain their vision (outside US markets)
	Antikatarata supplementary treatment of lens opacities (Russia only)

Vision Care

Through the integration of CIBA Vision products, Alcon is now one of the largest manufacturers of contact lenses and lens care products (not all products and indications are currently available in every country and are subject to local regulatory requirements and timing).

Contact Lenses	*Air Optix* family of silicone hydrogel contact lenses
	Dailies family of daily disposable contact lenses
	FreshLook family of color contact lenses
Contact Lens Care	*Opti-Free EverMoist* MPDS (*Opti-Free PureMoist* in US)
	Opti-Free RepleniSH Multi-Purpose Disinfecting Solution (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
	AcrySof IQ ReSTOR Toric IOL (new design)	Cataract	US 2014 EU 2012 Jpn 2014	Advanced development
	Next generation Phaco system	Cataract	US 2012 EU 2013 Jpn 2013	Advanced development
	AcrySof IQ ReSTOR Toric IOL	Cataract	US 2013 Jpn 2014	Advanced development
	AcrySof IQ ReSTOR Toric IOL diopter range expansion	Cataract	US 2013 Jpn 2014	Advanced development
	AcrySof IQ Toric IOL low diopter range expansion	Cataract	US 2013 Jpn 2014	Advanced development
	AcrySof Cachet angle-supported phakic lens	Refractive	US 2012[(1)] Jpn 2013	Advanced development
	Infiniti system upgrade	Cataract	US Filed Jpn 2012	Filed Advanced development
	Allegretto EX-500 laser, new indication	Refractive	US 2013	Advanced development
Ophthalmic Pharmaceuticals	*Azarga* solution	Glaucoma	Jpn 2012	Phase III
	New Combination	Glaucoma	US 2012 EU 2013	Phase III
	Travoprost, new formulation	Glaucoma	US 2013 EU 2013 Jpn 2013	Phase III
	Nepafenac, new formulation	Anti-inflammatory	U.S 2011 EU 2012	Filed Phase III
	Nepafenac, new indication	Anti-inflammatory	EU 2011	Filed
	Durezol emulsion, new indication	Anti-inflammatory	US 2011	Filed
	AL-2354A	Dry eye	US 2012	Phase III
	AL-43546	Dry eye	Jpn 2014	Phase III
	Olopatadine, new formulation	Ocular allergy	US 2014 or later	Phase III

		EU 2014 or later	
Cilodex	Otic infections	EU 2011	Filed
AL-60371	Otic infections	US 2013	Phase III
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Franchise	Project/Compound	Condition	Planned filing dates	Current phase
Vision Care	*Dailies Total 1* lens	Contact lens	US 2011 Jpn 2012	Filed Advanced development
	New Color Lens Design	Contact lens	EU 2011 Jpn 2011	Advanced development
	New Toric Lens Design	Contact lens	US 2012 E.U 2012 Jpn 2014	Advanced development
	New Multi-focal Design	Contact lens	US 2013 EU 2013 Jpn 2013	Advanced development
	New Color Lens Design	Contact lens	US 2012 EU 2012	Advanced development
	New lens solution	Lens solution	US 2013 EU 2013 Jpn 2014	Advanced development
	Lens comfort drop	Lens solution	US 2012 EU 2012	Advanced development

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

Principal Markets

The principal markets for our Alcon Division include the US, Americas (except the US) and Europe. The following table sets forth the aggregate 2011 net sales of the Alcon Division by region:

Alcon Division	2011 Net Sales to third parties	
	$ millions	%
United States	3,810	38.3
Americas (except the United States)	1,106	11.1
Europe	2,835	28.4
Rest of the World	2,207	22.2
Total	**9,958**	**100**

Sales of certain eye care Ophthalmic Pharmaceuticals products, including 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.

Research and Development

In 2011, the Alcon Division invested $892 million ($869 million excluding amortization and impairment charges) in research and development, which amounted to 9% of the Division's net sales. The Alcon Division invested $352 million ($351 million excluding amortization and impairment charges) in research and development in 2010.

The Alcon Division has approximately 2,000 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

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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 will engage in research activities in an effort to discover expanded 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.

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 Vision Care business benefits from the addition of CIBA Vision's contact lenses and lens care products to Alcon's existing lens care portfolio. Research and development activities for the combined business focuses on 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 and certain contact lens care products at seven facilities in the United States, Belgium, France, Spain, Brazil and Mexico. Additionally, Alcon recently completed construction on its new pharmaceutical plant in Singapore, which is targeted to start up in mid-2012. 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 also 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.

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.

The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. Like our competitors, our Alcon Division has faced manufacturing issues, and has received Warning Letters relating to such manufacturing issues.

For example, in late December 2010, CIBA Vision was issued a Warning Letter from the FDA regarding its Cidra, Puerto Rico manufacturing facility dedicated to producing CIBA Vision specialty soft contact lenses. CIBA Vision responded to the FDA concerns which were related to the need for additional documentation to support compliance in the areas of validation, corrective and preventative actions. In the second quarter of 2011, CIBA Vision discontinued its specialty soft contact lenses and closed its manufacturing facility in Cidra, Puerto Rico.

Marketing and Sales

Our Alcon Division conducts sales and marketing activities around the world in 75 countries organized under five operating regions (US, Europe/Middle East/Africa, Latin America/Caribbean/Canada, 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

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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.

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