NOVARTIS AG
Form 20-F
January 27, 2015

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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 20-F

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

OR

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

OR

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

OR

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

Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

Lichtstrasse 35
4056 Basel, Switzerland

(Address of principal executive offices)

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

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

Title of class	Name of each exchange on which registered
American Depositary Shares each representing 1 share	**New York Stock Exchange, Inc.**
Ordinary shares, nominal value CHF 0.50 per share*	**New York Stock Exchange, Inc.***

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

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

None

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

2,398,626,257 shares

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

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

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INTRODUCTION AND USE OF CERTAIN TERMS

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

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

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

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

FORWARD-LOOKING STATEMENTS

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

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

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

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

- unexpected regulatory actions or delays or government regulation generally, including an unexpected failure to obtain necessary government approvals for the transactions, or unexpected delays in obtaining such approvals;
- the potential that the strategic benefits, synergies or opportunities expected from the announced transactions, including the divestment of our former Animal Health Division to Lilly, may not be realized or may take longer to realize than expected;
- the inherent uncertainties involved in predicting shareholder returns or credit ratings;
- the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data;
- our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year;
- unexpected manufacturing or quality issues;
- global trends toward health care cost containment, including ongoing pricing pressures;
- uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, government investigations and intellectual property disputes;
- general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries;
- uncertainties regarding future global exchange rates, including as a result of recent changes in monetary policy by the Swiss National Bank;
- uncertainties regarding future demand for our products;
- uncertainties involved in the development of new healthcare products; and

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

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

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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, 2014, 2013 and 2012 are included in "Item 18. Financial Statements" in this Form 20-F.

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

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

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

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

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

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

Cash Dividends per Share

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

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

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

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

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Exchange Rates

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Bloomberg Market System. The exchange rate in effect on January 21, 2015, as found on Bloomberg Market System, was CHF 1.00 = $1.14.

Year ended December 31, ($ per CHF)	**Period End**	**Average[(1)]**	**Low**	**High**
2010	1.06	0.96	0.86	1.07
2011	1.06	1.13	1.06	1.25
2012	1.09	1.07	1.02	1.12
2013	1.12	1.08	1.05	1.12
2014	1.01	1.09	1.01	1.13
Month				
August 2014			1.09	1.11
September 2014			1.05	1.09
October 2014			1.03	1.06
November 2014			1.03	1.04
December 2014			1.01	1.04
January 2015 (through January 21, 2015)			0.98	1.16

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

3.B Capitalization and Indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk Factors

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

Risks Facing Our Business

Our products face important patent expirations and significant competition.

The products of our Pharmaceuticals and Alcon Divisions, as well as key products from our other divisions, are generally protected by patent rights, which are intended to provide us with exclusive rights to market the patented products. However, those patent rights are of varying strengths and durations. Loss of market exclusivity for one or more important products have had, and can be expected to continue to have a material adverse effect on our results of operations.

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The introduction of generic competition for a patented medicine typically results in a significant and rapid reduction in net sales and net income for the patented product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can result from the regular expiration of the term of the patent. Such competition can also result from the entry of generic versions of another medicine in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory licensing of our drugs by governments, or from a general weakening of intellectual property laws in certain countries around the world. In addition, generic manufacturers frequently take an aggressive approach to challenging patents, conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement, before final resolution of legal proceedings.

We also rely in all aspects of our businesses on unpatented proprietary technology, know-how, trade secrets and other confidential information, which we seek to protect through various measures including confidentiality agreements with licensees, employees, third-party collaborators, and consultants who may have access to such information. If these agreements are breached, our contractual remedies may not be adequate to cover any losses.

Some of our best-selling products have begun or are about to face significant competition due to the end of market exclusivity resulting from the expiry of patent protection.

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

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

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

Patent protection on rivastigmine, the active ingredient in *Exelon*, has expired and *Exelon* capsules are subject to generic competition in major markets, including the US and all of Europe. We hold additional patents with respect to *Exelon* Patch, which makes up a substantial portion of our *Exelon* sales, but these have been challenged. Generic versions of *Exelon* Patch are on the market in several European countries.

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

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In 2015, the impact of generic competition on our net sales is expected to be approximately $2.5 billion. Because we typically have substantially reduced marketing and research and development expenses related to a product in its final year of exclusivity, it is expected that the loss of patent protection will have an impact on our operating income which can be expected to correspond to a significant portion of the product's lost sales. The magnitude of such an impact could depend on a number of factors, including the time of year at which such exclusivity would be lost; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic competitor products approved, including whether, in the US, a single competitor is granted an exclusive marketing period, and whether an authorized generic is launched; and the geographies in which generic competitor products are approved, including the strength of the market for generic pharmaceutical products in such geographies and the comparative profitability of branded pharmaceutical products in such geographies.

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

Similarly, all of our businesses are faced with intense competition from new products and technological advances from competitors, including new competitors from other industries that are entering the healthcare field. Physicians, patients and third-party payers may choose our competitors' products instead of ours if they perceive them to be safer, more effective, easier to administer, less expensive, more convenient, or more cost-effective.

Products that compete with ours, including products competing against some of our best-selling products, are launched from time to time. We cannot predict with accuracy the timing of the introduction of such competitive products or their possible effect on our sales. However, products significantly competitive to our major products *Lucentis* and *Gilenya* have been launched. Such products, and other competitive products, could adversely affect the revenues from our products and our results of operations.

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

Our ability to continue to grow our business and to replace sales lost due to competition or to other sources depends in significant part upon the success of our research and development activities in identifying, and successfully and cost-effectively developing new products that address unmet medical needs, are accepted by patients and physicians, and are reimbursed by payors. To accomplish this, we commit substantial effort, funds and other resources across all our divisions to research and development, both through our own dedicated resources and through collaborations with third parties. Developing new healthcare products and bringing them to market, however, is a highly costly, lengthy and uncertain process. In spite of our significant investments, there can be no guarantee that our research and development activities will produce commercially viable new products that will enable us to grow our business and replace lost revenues and income.

Using the products of our Pharmaceuticals Division as an example, the research and development process for a new product can take up to 15 years, or even longer, from discovery to commercial product launch and with a limited available patent life, the longer it takes to develop a product, the less time there will be for us to recoup our development costs. New products need not only undergo intensive preclinical and clinical testing, but also must be approved by means of highly complex, lengthy and expensive approval processes which can vary from country to country. During each stage, there is a substantial risk that we will encounter serious obstacles which will further delay us and add substantial expense, that we will only develop a product with limited potential for commercial success, or that we will be forced to abandon a product in which we have invested substantial amounts of time and money. These

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risks may include: failure of the product candidate in preclinical studies; difficulty enrolling patients in clinical trials or delays or clinical trial holds at clinical trial sites; delays in completing formulation and other testing and work necessary to support an application for regulatory approval; adverse reactions to the product candidate or other safety concerns; insufficient clinical trial data to support the safety or efficacy of the product candidate; an inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-effective manner; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

In addition, following a series of widely publicized issues, health regulators have increased their focus on product safety. Governmental authorities and payors around the world have also paid increased attention to whether new products offer a significant benefit over other products in the same therapeutic class. These developments have led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has become even more challenging.

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

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

In addition, our Sandoz Division has made, and expects to continue to make, significant investments in the development of differentiated, "difficult-to-make" generic products, including biotechnology-based, "biologic" medicines intended for sale as bioequivalent or "biosimilar" generic versions of currently-marketed biotechnology products. While the development of such products typically is significantly less costly and complex than the development of the equivalent originator medicines, it is nonetheless significantly more costly and complex than for non-differentiated generic products. In addition, to date, many countries do not yet have a fully-developed legislative or regulatory pathway which would permit biosimilars to be brought to market or sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Significant difficulties in the development of differentiated products, further delays in the development of such regulatory pathways, or any significant impediments that may ultimately be built into such pathways, could put at risk the significant investments that Sandoz has made, and will continue to make, in the development of differentiated products in general, and in its biotechnology operations in particular, and could have a material adverse effect on the long-term success of the Sandoz Division and the Group as a whole.

If we are unable to cost-effectively maintain an adequate flow of successful new products and new indications for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by

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competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations. For a description of the approval processes which must be followed to market our products, see the sections headed "Regulation" included in the descriptions of our five operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

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

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly. These pressures are particularly strong given the persistently weak economic and financial environment in many countries and the increasing demand for healthcare resulting from the aging of the global population and the prevalence of behaviors that increase the risk of obesity and other chronic diseases. In addition, in certain countries, patients, healthcare providers and the media are increasingly raising questions about healthcare pricing issues. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. These ongoing pressures affect all of our divisions that rely on reimbursement including Pharmaceuticals, Alcon, Sandoz and Vaccines. They involve a number of cost-containment measures, such as government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing systems, payors limiting access to treatments based on cost-benefit analyses, an increase in imports of drugs from lower-cost countries to higher-cost countries, shifting of the payment burden to patients through higher co-payments, limiting physicians' ability to choose among competing medicines, mandatory substitution of generic drugs for the patented equivalent, and growing pressure on physicians to reduce the prescribing of patented prescription medicines.

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

We expect these pressures to continue in 2015 as healthcare payors around the globe, including government-controlled health authorities, insurance companies and managed care organizations, step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price cuts. For more information on price controls and on our challenging business environment see "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls."

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

We are obligated to comply with the laws of all of the countries around the world in which we operate and sell products with respect to an extremely wide and growing range of activities, as well as with new requirements imposed on us from time to time as government and public expectations regarding acceptable corporate behavior change. For example, there are new laws in the US and in other countries around the world that require us to be more transparent with respect to our interactions with healthcare professionals. To help us in our efforts to comply with the many requirements that impact us, we have a significant global ethics and compliance program in place, and we devote substantial time and resources to efforts to ensure that our business is conducted in a lawful and publicly acceptable manner. Nonetheless, despite our efforts, any failure to comply with law or with heightened public expectations could lead to

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substantial liabilities that may not be covered by insurance, or to other significant losses, and could affect our business and reputation.

In particular, in recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the US and in an increasing number of countries around the world. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, such as proceedings regarding sales and marketing practices, product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, health and safety, environmental, tax, privacy, and intellectual property matters. Such proceedings are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations or cash flows.

In addition, governments and regulatory authorities around the world have been stepping up their compliance and law enforcement activities in recent years in key areas, including sales and marketing practices, corruption, trade restrictions, embargo legislation, insider trading, antitrust, and data privacy, and are increasingly challenging practices previously considered to be legal. Responding to such investigations is costly, and requires an increasing amount of management's time and attention. In addition, such investigations may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the US and other countries, and may lead to litigation and monetary penalties. These factors have contributed to decisions by us and other companies in our industry, when deemed in their interest, to enter into settlement agreements with governmental authorities around the world prior to any formal decision by the authorities. These settlements have involved and may continue to involve large cash payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, settlements of healthcare fraud cases in the US and other countries sometimes require companies to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for a period of years. Our affiliate Novartis Pharmaceuticals Corporation is a party to such an agreement, which is scheduled to expire in 2015. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

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

Our businesses are currently subject to a number of these cases and governmental investigations, as well as information requests by regulatory authorities. For more detail regarding specific legal matters currently pending against us and provisions for such matters, see "Item 18. Financial Statements Note 20." See also " Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses" below. Adverse judgments or settlements in any of the significant investigations or cases against us could have a material adverse effect on our business, financial condition and results of operations.

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

The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. Whether our products are manufactured at our own dedicated manufacturing facilities or by third parties, we must ensure that all manufacturing processes comply with current Good Manufacturing Practices (cGMP) and other applicable regulations, as well as with our own high quality

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standards. In recent years, health authorities have intensified their scrutiny of manufacturers' compliance with such requirements, and are increasingly challenging practices that were previously considered acceptable. If we or our third-party suppliers fail to comply fully with these requirements and the health authorities' expectations, then we could be required to shut down our production facilities or production lines, or could be prevented from importing our products from one country to another. This could lead to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. And such shortages or shut downs have led to and could continue to lead to significant losses of sales revenue and to potential third-party litigation. In addition, health authorities have in some cases imposed significant penalties for such failures to comply with cGMP. A failure to comply fully with cGMP could also lead to a delay in the approval of new products to be manufactured at the impacted site.

Like our competitors, we have faced significant manufacturing issues in recent years. As a result of such issues, we were unable to supply certain products to the market for significant periods of time, and suffered significant losses in sales and market share. These supply issues have required us to outsource the production of certain key products that were previously manufactured in our own production facilities, which may limit the potential profitability of such products. In addition, to meet health authority and our own high quality standards, we have expended considerable resources to upgrade and remediate issues at our sites.

In addition, to meet increasing health authority expectations, we are devoting substantial time and resources to improve quality and assure consistency of product supply at our manufacturing sites around the world. Ultimately, there can be no guarantee of the outcome of these efforts. Nor can there be any guarantee that we will not again face significant manufacturing issues, or that we will successfully manage such issues when they arise.

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

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

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

In sum, a disruption in the supply of certain key products whether as a result of a failure to comply with applicable regulations or health authority expectations, the fragility of the production process, natural or man-made disasters at one of our facilities or at a critical supplier or vendor, or our failure to accurately predict demand could have a material adverse effect on our business, financial condition or results of operations. See also " Earthquakes and other natural disasters could adversely affect our business," below.

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The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. In addition, these issues may be further impacted by the unsettled political conditions currently existing in the US, Europe and other places. Such uncertain times may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. For example, persistent financial weakness in certain countries in Europe has increased pressures on those countries, and on payors in those countries, to force healthcare companies to decrease the prices at which we may sell them our products. See also "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls." Concerns continue that payors in some countries, including Greece, Italy, Portugal and Spain, may not be able to pay us in a timely manner. Certain other countries, such as Venezuela have taken steps to introduce exchange controls and limit companies from distributing retained earnings or paying intercompany payables due from those countries. See also, "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources," "Item 18. Financial Statements Notes 15 and 29."

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. Although we make efforts to monitor these third parties' financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to payment risks from business interactions directly with fiscally-challenged government payers. See also " Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses" below.

In addition, the varying effects of difficult economic times on the economies, currencies and financial markets of different countries has impacted, and may continue to unpredictably impact, the conversion of our operating results into our reporting currency, the US dollar, as well as the value of our investments in our pension plans. See " Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," below, and " If any of numerous key assumptions and estimates in calculating our pension plan obligations turn out to be different from our actual experience, we may be required to increase substantially our contributions to pension plans as well as our pension-related costs in the future," below. In addition, the financial situation may also result in a lower return on our financial investments, and a lower value on some of our assets. Alternately, inflation could accelerate, which could lead to higher interest rates, which would increase our costs of raising capital.

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

At the same time, significant changes and volatility in the financial markets, in the consumer and business environment, in the competitive landscape and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any

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revenue or earnings guidance or outlook which we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current knowledge and conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

In addition, increasing political and social instability around the world, including political instability and military action involving Russia, Ukraine and parts of the Middle East, the impacts of the Ebola crisis in western Africa, increased political and religious radicalism in many places, and increasing social unrest, including anti-immigrant activities in many countries may lead to significant business disruptions or other adverse business conditions. Similarly, increased scrutiny of corporate taxes and executive pay may lead to significant business disruptions or other adverse business conditions, and may interfere with our ability to attract and retain qualified personnel. See " An inability to attract and retain qualified personnel could adversely affect our business" below.

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

Changes in exchange rates between the US dollar, our reporting currency, and other currencies can result in significant increases or decreases in our reported sales, costs and earnings as expressed in US dollars, and in the reported value of our assets, liabilities and cash flows. This in turn may significantly affect the comparability of period-to-period results of operations. In 2014, the US dollar significantly increased in value against most currencies. In particular, the average value of the Japanese yen and emerging market currencies (especially the ruble) decreased in 2014 against the US dollar. However, in January 2015, following an announcement by the Swiss National Bank that it was discontinuing its minimum exchange rate with the euro, the value of the Swiss franc increased substantially. Because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including expenditures in Swiss francs that are significantly higher than our revenues in Swiss francs, such exchange rate volatility can have a significant impact on the reported value of our net sales, earnings, assets and liabilities, and the timing and extent of such volatility can be difficult to predict.

In addition, there is a risk that certain countries could take other steps which could significantly impact the value of their currencies. Such steps could include "quantitative easing" measures, potential withdrawals by countries from common currencies or the setting of exchange controls, as Venezuela did. Should such steps significantly change the value of a country's currency, then this could impact the value in US dollars of our sales and earnings in such countries, as well as the currency translation adjustments included in our consolidated equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources Effects of Currency Fluctuations" "Item 11. Quantitative and Qualitative Disclosures about Market Risk", and "Item 18. Financial Statements Note 29."

We may not successfully achieve our goals in strategic transactions or reorganizations, including the portfolio transformation transactions and the formation of Novartis Business Services.

As part of our strategy, from time to time we evaluate and pursue potential strategic business acquisitions and divestitures to expand or complement our existing businesses, or to enable us to focus more sharply on our strategic businesses. We cannot ensure that suitable acquisition candidates will be identified. Acquisition activities can be thwarted by overtures from competitors for the targeted assets, potentially increasing prices demanded by sellers, governmental regulation (including market concentration limitations) and replacement product developments in our industry. Once an acquisition is agreed upon with a third party, we may not be able to complete the acquisition in the expected form or within the expected time frame, or at all, due to a failure to obtain required regulatory approvals or a failure to achieve contractual or other required closing conditions. Further, after an acquisition, efforts to integrate the business may not meet expectations, or may otherwise not be successful, as a result of

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corporate cultural differences, difficulties in retention of key personnel, customers and suppliers, coordination with other products and processes, or other reasons. Also, acquisitions and divestments could divert management's attention from our existing businesses, and could result in the existing businesses failing to achieve expected results, or in liabilities being incurred that were not known at the time of acquisition, or the creation of tax or accounting issues. Similarly, we cannot ensure that suitable buyers will be identified for businesses or other assets that we might want to divest. Neither can we ensure that we will correctly select businesses or assets as candidates for divestiture, that we will be able to successfully complete any agreed upon divestments, or that any expected strategic benefits, synergies or opportunities will arise as a result of any divestiture.

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

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

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

In addition, in April 2014, we announced the creation of a shared services organization, Novartis Business Services (NBS), which became effective on July 1, 2014. NBS consolidated a number of business support services previously spread across divisions, including Information Technology, Financial Reporting and Accounting Operations, Real Estate & Facility Services, Procurement, Payroll and Personnel Administration and the Pharmaceuticals Global Business Services. This reorganization was designed to improve profitability and free up resources that could be reinvested in growth and innovation, and to allow our divisions to focus more on customer-facing activities. But the expected benefits of this reorganization may never be fully realized or may take longer to realize than expected. There can be no certainty that the numerous business functions involved will be successfully integrated into a single organization and that key personnel will be retained. Disruption from the reorganization may make it more difficult to maintain relationships with customers, employees or suppliers.

Both with respect to the transactions and reorganizations previously announced, and to potential future transactions and reorganizations, if we fail to timely recognize or address these risks, or to devote

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adequate resources to them, we may fail to achieve our strategic objectives, including our growth strategy, or otherwise may not realize the intended benefits of the acquisition, divestiture or reorganization.

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

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

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets, investments in associated companies and goodwill, for impairment. Goodwill, acquired research and development, and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. Impairment testing under IFRS may lead to impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations and financial condition. In 2014, for example, we recorded intangible asset and goodwill impairment charges of $752 million. Of this, $334 million was recorded on the announcement of the sale of our influenza vaccines business to CSL. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing impact of impairment charges on our results of operations, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Impairment of Goodwill, Intangible Assets and Property, Plant and Equipment" and "Item 18. Financial Statements Notes 1 and 11."

Our indebtedness could adversely affect our operations.

As of December 31, 2014 we had $13.8 billion of non-current financial debt and $6.6 billion of current financial debt. Our current and long-term debt requires us to dedicate a portion of our cash flow to service interest and principal payments and may limit our ability to engage in other transactions and otherwise may place us at a competitive disadvantage relative to our competitors that have less debt. We may have difficulty refinancing our existing debt or incurring new debt on terms that we would consider to be commercially reasonable, if at all.

Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses.

We invest a significant amount of effort and resources into outsourcing and offshoring certain key business functions with third parties, including research and development collaborations, manufacturing operations, warehousing, distribution activities, certain finance functions, marketing activities, data management and others. Our reliance on outsourcing and third parties for certain functions, such as the research and development or manufacturing of products, may limit the potential profitability of such products. In addition, despite contractual relationships with the third parties to whom we outsource these functions, we cannot ultimately control how they perform their contracts. Nonetheless, we depend on these third parties to achieve results which may be significant to us. If the third parties fail to meet their obligations or to comply with the law, we may lose our investment in the collaborations and fail to receive the expected benefits. In addition, should any of these third parties fail to comply with the law in the course of their performance of services for us, there is a risk that we could be held responsible for such violations of law, as well. Any such failures by third parties could have a material adverse effect on our business, financial condition or results of operations.

In particular, in many countries, including many developing markets, we rely heavily on third party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to those within our organization. Some of these countries are plagued by corruption. If our efforts to screen our third party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties

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with applicable laws and regulations, which may have a material adverse effect on our reputation and on our business, financial condition or results of operations.

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

At a time of slowing growth in sales of healthcare products in industrialized countries, many emerging markets have experienced proportionately higher sales growth and an increasing contribution to the industry's global performance. In 2014, we generated $15.3 billion, or approximately 26% (2013: 26%) of our net sales from Emerging Growth Markets which comprise all markets other than the Established Markets of the US, Canada, Western Europe, Japan, Australia and New Zealand as compared with $42.7 billion, or approximately 74% (2013: 74%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 11% in constant currencies in 2014, compared to 1% sales growth in constant currencies in the Established Markets during the same period. As a result of this trend, we have been taking steps to increase our activities in the Emerging Growth Markets, and have been making significant investments in our businesses in those countries.

There is no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will continue to experience growth rates in excess of the world's largest markets. Some Emerging Growth Market countries may be especially vulnerable to the effects of the persistently weak global financial environment, may have very limited resources to spend on healthcare or are more susceptible to political and social instability. See " The persistently weak global economic and financial environment in many countries may have a material adverse effect on our results" above. Many of these countries are subject to increasing political and social pressures, including from a growing middle class seeking increased access to healthcare. Such pressures on local government may in turn result in an increased focus by the governments on our pricing, and may put at risk our intellectual property.

These countries also may have a relatively limited number of persons with the skills and training suitable for employment at an enterprise such as ours. See " An inability to attract and retain qualified personnel could adversely affect our business" below. In some Emerging Growth Market countries, a culture of compliance with law may not be as fully developed as in the Established Markets China's investigations of the activities of multinational healthcare companies have been well publicized or we may be required to rely on third-party agents, in either case putting us at risk of liability. See " Failure to comply with law, and resulting investigations and legal proceedings may have a significant negative effect on our results of operations," and " Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses," above.

In addition, many of these countries have currencies that may fluctuate substantially. If these currencies devalue significantly against the US dollar, and we cannot offset the devaluations with price increases, then our products may become less profitable, or may otherwise impact our reported financial results. See " Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," above.

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

Failure to obtain marketing exclusivity periods for new generic products, or to develop differentiated products, as well as intense competition from patented and generic 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 for first-to-file generics and when it is able to develop differentiated products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz. In addition, the division faces

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intense competition from companies that market patented pharmaceutical products, which sometimes take aggressive steps to prevent or delay the introduction of generic medicines, to limit the availability of exclusivity periods or to reduce their value, and from other generic pharmaceuticals companies, which aggressively compete for exclusivity periods and for market share of generic products that may be identical to certain of our generic products. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction. See also " Our research and development efforts may not succeed in bringing new products to market, or may fail to do so cost-efficiently enough, or in a manner sufficient to grow our business and replace lost revenues and income" above, with regard to the risks involved in our efforts to develop differentiated generic products.

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

We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. We are required to make significant assumptions and estimates about future events in calculating the present value of expected future expenses and liabilities related to these plans. These include assumptions about discount rates we apply to estimated future liabilities and rates of future compensation increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by Novartis may differ materially from the actual results we experience due to changing market and economic conditions (including the effects of the persistently weak global financial environment, which, to date, have resulted in extremely low interest rates in many countries), higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the interest rate we apply in determining the present value of expected future defined benefit obligations of one-quarter of one percent would have increased our year-end defined benefit pension obligation for plans in Switzerland, US, UK, Germany and Japan, which represent about 95% of the Group total defined benefit pension obligation, by $0.8 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. Further, additional employer contributions might be required if plan funding falls below the levels required by local rules. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Retirement and other post-employment benefit plans" and "Item 18. Financial Statements Note 25". See also " The persistently weak global economic and financial environment in many countries may have a material adverse effect on our results" above.

Changes in tax laws or their application could adversely affect our results of operations.

The integrated nature of our worldwide operations enables us to achieve an attractive effective tax rate on our earnings because a portion of our earnings are earned in jurisdictions which tax profits at more favorable rates. Changes in tax laws or in the laws' application, including with respect to tax base or rate, transfer pricing, intercompany dividends and cross-border transactions, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, could increase our effective tax rate and adversely affect our financial results.

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

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can potentially be life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could

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materially affect patient confidence in the authentic product, and harm the business of companies such as ours or lead to litigation. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm.

Ongoing consolidation among our distributors and retailers is increasing both the purchasing leverage of key customers and the concentration of credit risk.

Increasingly, a significant portion of our global sales are made to a relatively small number of US drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally are all in the US, and accounted for approximately 15%, 13% and 6%, respectively, of Group net sales in 2014. The largest trade receivables outstanding were for these three customers, amounting to 11%, 8% and 4%, respectively, of the Group's trade receivables at December 31, 2014. The trend has been toward further consolidation among distributors and retailers, both in the US and internationally. As a result, our customers are gaining additional purchasing leverage, which increases the pricing pressures facing our businesses. Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantially greater than in the past. This could have a material adverse effect on our business, financial condition and results of operations.

An inability to attract and retain qualified personnel could adversely affect our business.

We highly depend upon skilled personnel in key parts of our organization, and we invest heavily in recruiting, training and retaining qualified individuals. The loss of the service of key members of our organization including senior members of our scientific and management teams, high-quality researchers and development specialists, and skilled personnel in emerging markets could delay or prevent the achievement of major business objectives.

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

Emerging markets are expected to be a driving force in global growth, but in countries like Russia and China there is a limited pool of executives with the training and international experience needed to work successfully in a global organization like Novartis. Moreover, many members of younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles. Geographic mobility is expected to decrease, and talented individuals in emerging countries anticipate ample career opportunities closer to home than in the past.

In addition, our ability to hire qualified personnel also depends on the flexibility to reward superior performance and to pay competitive compensation. Laws and regulations on executive compensation, including legislation in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel.

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

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

Our business is heavily dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of these systems make them potentially vulnerable to breakdown, malicious intrusion, malware and other cyber-attacks. While we have invested heavily in the protection of our data and information technology, we may not be able to prevent breakdowns or breaches in our systems that could adversely affect our business.

Any such events could negatively impact important business processes such as the conduct of scientific research and clinical trials, the submission of the results of such efforts to health authorities in support of requests for product approvals, the functioning of our manufacturing and supply chain processes, our compliance with legal obligations and other key business activities. In addition, such potential information technology issues could lead to the loss of important information such as trade secrets or other intellectual property, or personal information (including sensitive personal information) of our employees, clinical trial patients, vendors, customers, collaborators and others, or could expose such important information to unauthorized persons. We also manufacture and sell a number of devices that make significant use of information technology, including our Alcon surgical equipment. Malfunctions in such technology could lead to a risk of harm to patients.

Any such breaches of data security or information technology disruptions could have a material adverse effect on our business, financial condition and results of operations.

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

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

Environmental liabilities may adversely impact our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on us to remediate contaminated sites. While we have set aside substantial provisions for worldwide environmental liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts for which we have provided in the Group consolidated financial statements. If we are required to further increase our provisions for environmental liabilities in the future, or if we fail to properly manage the safety of our facilities and the environmental risks, this could have a material adverse effect on our business, financial condition and results of operations. For more detail regarding environmental matters, see "Item 4.D Property, Plants and Equipment Environmental Matters" and "Item 18. Financial Statements Note 20."

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Earthquakes and other natural disasters could adversely affect our business.

In recent years, extreme weather events and changing weather patterns such as storms, flooding, drought, and temperature changes, appear to have become more common. We operate in countries around the world. As a result, we are potentially exposed to varying natural disaster risks like hurricanes, tornadoes or floods. As a result of these and other potential impacts of climate change on the environment, we could experience business interruptions, destruction of facilities and loss of life, all of which could have a material adverse effect on our business, financial condition and results of operations could be put at risk.

Our corporate headquarters, the headquarters of our Pharmaceuticals Division, and certain of our major Pharmaceuticals Division production and research facilities are located near earthquake fault lines in Basel, Switzerland. In addition, other major facilities of several divisions are located near major earthquake fault lines in various locations around the world. In the event of a major earthquake, we could experience business interruptions, destruction of facilities and loss of life, all of which could have a material adverse effect on our business, financial condition and results of operations. See also " The manufacture of our products is highly regulated and complex, and may result in a variety of issues that could lead to extended supply disruptions and significant liability," above.

Risks Related To Our ADRs

The price of our ADRs and the US dollar value of any dividends may be negatively affected by fluctuations in the US dollar/Swiss franc exchange rate.

Our American Depositary Shares (ADSs) each representing one Novartis share and evidenced by American Depositary Receipts (ADRs) trade on the NYSE in US dollars. Since the shares underlying the ADRs are listed in Switzerland on the SIX Swiss Exchange (SIX) and trade in Swiss francs, the value of the ADRs may be affected by fluctuations in the US dollar/Swiss franc exchange rate. In addition, since dividends that we may declare will be denominated in Swiss francs, exchange rate fluctuations will affect the US dollar equivalent of dividends received by holders of ADRs. If the value of the Swiss franc decreases against the US dollar, the price at which our ADRs trade may and the value of the US dollar equivalent of any dividend will decrease accordingly.

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

Under Swiss law, shareholders have preemptive rights to subscribe for issuances of new shares on a *pro rata* basis. Shareholders may waive their preemptive rights in respect of any offering at a general meeting of shareholders. Preemptive rights, if not previously waived, are transferable during the subscription period relating to a particular offering of shares and may be quoted on the SIX. US holders of ADRs may not be able to exercise the preemptive rights attached to the shares underlying their ADRs unless a registration statement under the US Securities Act of 1933 is effective with respect to such rights and the related shares, or an exemption from this registration requirement is available. In deciding whether to file such a registration statement, we would evaluate the related costs and potential liabilities, as well as the benefits of enabling the exercise by ADR holders of the preemptive rights associated with the shares underlying their ADRs. We cannot guarantee that a registration statement would be filed, or, if filed, that it would be declared effective. If preemptive rights could not be exercised by an ADR holder, JPMorgan Chase Bank, N.A., as depositary, would, if possible, sell the holder's preemptive rights and distribute the net proceeds of the sale to the holder. If the depositary determines, in its discretion, that the rights could not be sold, the depositary might allow such rights to lapse. In either case, the interest of ADR holders in Novartis would be diluted and, if the depositary allowed rights to lapse, holders of ADRs would not realize any value from the preemptive rights.

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Item 4. Information on the Company

4.A History and Development of Novartis

Novartis AG

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

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

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

Important Corporate Developments 2012-2014

2014

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

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April	Novartis announces a set of definitive inter-conditional agreements with GSK. Under these agreements, Novartis would acquire GSK oncology products and certain related assets, would be granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline (excluding oncology vaccines) and would divest the Vaccines Division (excluding its influenza vaccines business) to GSK. The two companies would also create a joint venture in consumer healthcare, of which Novartis would own 36.5%.
	Novartis also announces a definitive agreement with Lilly to divest the Company's Animal Health Division. This divestment was completed on January 1, 2015.
	Novartis announces the creation of a shared services organization, Novartis Business Services (NBS). NBS consolidates a number of business support services previously spread across divisions, including Information Technology, Financial Reporting and Accounting Operations, Real Estate & Facility Services, Procurement, Payroll and Personnel Administration and the Pharmaceuticals Global Business Services. This reorganization was designed to improve profitability and free up resources that could be reinvested in growth and innovation, and to allow our divisions to focus more on customer-facing activities. NBS became effective on July 1, 2014.
February	Novartis announces the acquisition of CoStim Pharmaceuticals Inc., a Cambridge, Massachusetts-based, privately held biotechnology company focused on cancer immunotherapy. The acquisition brings to Novartis late discovery stage immunotherapy programs directed to several targets, including PD-1.
	Novartis appoints a Global Head, Corporate Responsibility reporting directly to the CEO.
January	Novartis implements several changes to its governance structure. These include elimination of the Chairman's Committee of the Novartis AG Board of Directors; transfer of operational responsibilities that previously rested with the Chairman or the Chairman's Committee, such as approval authority for management compensation, to the CEO or the Executive Committee; and establishment of the Research and Development Committee of the Novartis AG Board of Directors to oversee Novartis research and development strategy and advise the Board on scientific trends and activities.

2013

November	Novartis announces a $5.0 billion share buyback. The buyback begins on the date of the announcement and will be executed over two years on the second trading line.
	Novartis announces a definitive agreement to divest its blood transfusion diagnostics unit to Grifols S.A. of Spain, for $1.7 billion. This transaction was completed in January 2014.
	Novartis announces that it will co-locate certain scientific resources in order to improve the efficiency and effectiveness of its global research organization. Changes include establishing a respiratory research group in Cambridge, Massachusetts, a proposal to close the Horsham, UK, research site, a plan to exit from the Vienna, Austria research site, consolidation of the US-based component of oncology research from Emeryville, California to Cambridge, Massachusetts, closure of the biotherapeutics development unit in La Jolla, California, and a plan to exit research in topical applications for dermatology.
September	Novartis announces that it has entered into an exclusive global licensing and research collaboration agreement with Regenerex LLC, a biopharmaceutical company based in Louisville, Kentucky, for use of the company's novel Facilitating Cell Therapy (FCRx) platform.
August	Joerg Reinhardt, Ph.D., assumes role of Chairman of the Board of Directors of Novartis AG on August 1.

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July	The Novartis Board of Directors announces a final agreement with its former Chairman, Dr. Daniel Vasella. From the date of the Annual General Meeting held on February 22, 2013, until October 31, 2013, Dr. Vasella was to provide certain transitional services, including select Board mandates with subsidiaries of Novartis and support of the ad-interim Chairman and the new Chairman. For his transitional services during such period, Dr. Vasella would receive cash of CHF 2.7 million, and 31,724 unrestricted shares as of October 31, 2013 (the market value of the shares as of the date of the announcement was approximately CHF 2.2 million). In addition, from November 1, 2013, to December 31, 2016, Dr. Vasella will receive a minimum of $250,000 per annum in exchange for making himself available to Novartis, at Novartis' request and discretion, to provide specific consulting services, such as the coaching of high-potential associates of Novartis and speeches at key Novartis events at a daily fee rate of $25,000, which will be offset against the $250,000 minimum annual payment. During November and December 2013, Dr. Vasella did not provide any coaching to associates and did not receive any compensation for this period.
	Novartis announces that it has entered into a development and licensing agreement with Biological E Limited (BioE), a biopharmaceutical company based in India, for two vaccines to protect against typhoid and paratyphoid fevers. The agreement advances the Novartis goal to deliver accessible and affordable vaccines that address unmet medical need in endemic regions.
April	Novartis and Malaria No More, a leading global charity determined to end malaria deaths, announce that they are joining forces on the Power of One campaign to help close the treatment gap and accelerate progress in the fight against malaria. Over the next three years, Novartis will support the campaign financially and also donate up to three million full courses of its pediatric antimalarial drug to match the treatments donated by the public, doubling the impact of these donations.
February	Novartis announces that the Novartis AG Board of Directors and Dr. Vasella agreed to cancel his non-competition agreement and all related conditional compensation. The agreement was to take effect after Dr. Vasella stepped down as Chairman of the Board at the Novartis Annual General Meeting on February 22, 2013.
January	Novartis announces that, at his own wish, Novartis AG Chairman of the Board of Directors Dr. Daniel Vasella will not stand for re-election as a member of the Board of Directors at the Annual General Meeting to be held on February 22, 2013. The Board of Directors proposed the election of, among others, Joerg Reinhardt, Ph.D., as a member of the Board for a term of office beginning on August 1, 2013, and ending on the day of the Annual General Meeting in 2016. The Board announced its intention to elect Joerg Reinhardt as Chairman of the Board of Directors as from August 1, 2013. The Board of Directors further announced its intention to elect its current Vice-Chairman, Ulrich Lehner, Ph.D., as Chairman of the Board of Directors for the period from February 22, 2013, until the new Chairman took office.
2012	
September	Novartis successfully completes a $2.0 billion bond offering in two tranches.
August	Novartis and the University of Pennsylvania (Penn) form a broad-based Research & Development alliance to advance novel T-cell immunotherapies to treat cancer. Novartis and Penn enter into a multi-year collaboration to study chimeric antigen receptor (CAR) technology for the treatment of cancer. The parties establish a joint Center for Advanced Cellular Therapies at Penn to develop and manufacture CARs. Novartis licenses worldwide rights to the first CAR investigational therapy, CART-19, from Penn, and obtains worldwide commercial rights to products from the collaboration. Novartis will provide an up-front payment to Penn, research funding, funding for the establishment of the CACT and milestone payments for the achievement of certain clinical, regulatory and commercial milestones and royalty payments.

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May	Sandoz announces an agreement to acquire Fougera Pharmaceuticals, based in Melville, New York, for $1.525 billion, to make Sandoz the number one generic dermatology medicines company globally and in the US, and to strengthen Sandoz's differentiated products strategy. The acquisition was completed in July 2012.
March	Alcon gains exclusive rights outside the US to ocriplasmin, a potential first pharmacological treatment for vitreomacular adhesion. Alcon pays ThromboGenics an upfront payment of EUR 75 million, with potential additional payments based on milestones, and on royalties on sales.
January	Novartis extends its commitment to help achieve the final elimination of leprosy. Our new five-year commitment includes a donation of treatments worth an estimated $22.5 million, and is expected to reach an estimated 850,000 patients. Novartis will also intensify efforts to build a multi-stakeholder initiative in a final push against leprosy. We have a long history in fighting leprosy, donating medicines and developing programs to support patients, valued at more than $100 million since 1986.
	Novartis announces the restructuring of its US Pharmaceuticals business to strengthen its competitive position in light of the loss of patent protection for *Diovan* and the expected impact on the worldwide sales of *Tekturna/Rasilez* after the termination of the ALTITUDE study. The restructuring of the US General Medicines business results in a reduction of 1,960 positions and leads to an exceptional charge of $160 million in the first quarter of 2012 and to expected annual savings of approximately $450 million by 2013.

For information on our principal expenditures on property, plants and equipment, see "Item 4. Information on the Company 4.D Property, Plants and Equipment." For information on our significant investments in research and development, see the sections headed "Research and Development" included in the descriptions of our operating divisions under "Item 4. Information on the Company 4.B Business Overview." For information on other principal capital expenditures and divestitures, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Factors Affecting Comparability of the Year-On-Year Results of Operations Recent Significant Transactions." For more information on the proposed transactions with GSK, the proposed transaction with CSL, or the completed transaction with Lilly, see "Item 4.B Business Overview Overview" and "Item 10.C Material Contracts."

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 over-the-counter products.

On April 22, 2014, Novartis announced that it had reached definitive agreements with GSK and Lilly on a set of transactions intended to transform our portfolio of businesses.

In inter-conditional transactions with GSK, Novartis agreed to: (1) acquire GSK oncology products and certain related assets, and was granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines; (2) create a joint venture with GSK in consumer healthcare by combining the Novartis OTC Division with the GSK consumer healthcare business, of which Novartis would own 36.5% and would have four of eleven seats on the joint venture's Board; and (3) divest the Vaccines Division (excluding the influenza vaccines business) to GSK. In addition, Novartis agreed to divest the Animal Health Division to Lilly. The divestment of our Animal Health Division to Lilly was completed on January 1, 2015.

On October 26, 2014, Novartis announced that it had reached a definitive agreement with CSL of Australia to divest its influenza vaccines business for $275 million.

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The transactions with GSK and CSL are subject to closing conditions and regulatory approvals. The transactions with GSK are expected to close in the first half of 2015, and the transaction with CSL is expected to close in the second half of 2015.

The Group's wholly-owned businesses are organized into five global operating divisions, and we report our results in the following five segments. In addition, we separately report Corporate activities. Following the announcement of the transactions with GSK and Lilly, in order to comply with IFRS, Novartis has separated the Group's reported financial data for the current and prior year into "continuing" operations and "discontinuing" operations:

Continuing Operations:

- Pharmaceuticals: Innovative patent-protected prescription medicines
- Alcon: Surgical, ophthalmic pharmaceutical and vision care products
- Sandoz: Generic pharmaceuticals
- Corporate activities

Discontinuing Operations:

- Vaccines: Preventive human vaccines and the blood transfusion diagnostics unit, which was divested on January 9, 2014
- Consumer Health: OTC (over-the-counter medicines) (following the January 1, 2015 completion of the divestment of our Animal Health Division to Lilly, the Consumer Health segment now consists only of the OTC Division)
- Corporate: certain transactional and other expenses related to the portfolio transformation

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

We separately report the financial results of our Corporate activities as part of our Continuing Operations. Income and expenses relating to Corporate include the costs of the Group headquarters and those of corporate coordination functions in major countries. In addition, Corporate includes other items of income and expense which are not attributable to specific segments such as certain expenses related to post-employment benefits, environmental remediation liabilities, charitable activities, donations and sponsorships.

Our divisions are supported by Novartis Business Services and the Novartis Institutes for BioMedical Research.

- Novartis Business Services (NBS) was launched in July 2014 with the transfer of over 7,000 associates, and organizational structures are being implemented to start operations in January 2015 as a shared services organization. NBS is designed to enhance profitability by harmonizing high-quality services at better price across the Group and Divisions. It covers approximately $6 billion in expenses, and synergies generated by the organization are expected to improve margin over time.
- The Novartis Institutes for BioMedical Research (NIBR) was created in 2003, and is headquartered in Cambridge, Massachusetts. More than 5,900 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, UK, Italy, Singapore and China. For more information about NIBR, see " Pharmaceuticals Research

and Development Research program," below.

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Novartis achieved net sales of $58.0 billion in 2014, while net income amounted to $10.3 billion. Research & Development expenditure in 2014 amounted to $9.9 billion ($9.6 billion excluding impairment and amortization charges). Of the Group's total net sales, $15.3 billion, or 26%, came from Emerging Growth Markets, and $42.7 billion, or 74%, came from Established Markets. Emerging Growth Markets comprise all markets other than the Established Markets of the US, Canada, Western Europe, Japan, Australia and New Zealand.

Headquartered in Basel, Switzerland, our Group companies employed 133,413 full-time equivalent associates as of December 31, 2014. Our products are available in approximately 180 countries around the world.

Continuing Operations:

Pharmaceuticals Division

Pharmaceuticals researches, develops, manufactures, distributes and sells patented prescription medicines and is organized in the following franchises: Oncology, Cardio-metabolic, Immunology and Dermatology, Retina, Respiratory, Neuroscience and Established Medicines. In 2014, our Pharmaceuticals Division also created a unit focused on the development and commercialization of Cell and Gene Therapies.

The preceding list reflects a new composition of therapeutic areas implemented within our Pharmaceuticals Division in the fourth quarter of 2014. The tables and product descriptions set forth below in " Pharmaceuticals," already reflect this new organizational structure. However, other sections of this Form 20-F still reflect the prior therapeutic areas. This includes the discussions and certain historical information provided in "Item 5. Operating and Financial Review and Prospects." and "Item 18. Financial Statements."

On April 22, 2014, we announced that we have agreed to acquire GSK oncology products and certain related assets for an aggregate cash consideration of $16 billion. Up to $1.5 billion of this cash consideration is contingent on certain development milestones. In addition, under the terms of the agreement we were granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines. The right of first negotiation is for a period of twelve and one half years from the acquisition closing date. We expect this transaction to close during the first half of 2015. This transaction is inter-conditional with the other announced transactions with GSK described under " Vaccines Division" and " Consumer Health."

In 2014, the Pharmaceuticals Division accounted for $31.8 billion, or 55%, of Group net sales, and for $8.5 billion, or 77%, of Group operating income (excluding Corporate income and expense, net).

Alcon Division

Our Alcon Division researches, develops, manufactures, distributes and sells eye care products and technologies to serve the full life cycle of eye care needs. Alcon offers a broad range of products to treat many eye diseases and conditions, and is organized into three franchises: Surgical, Ophthalmic Pharmaceuticals and Vision Care. The Surgical portfolio includes technologies and devices for cataract, retinal, glaucoma and refractive surgery, as well as intraocular lenses to treat cataracts and refractive errors, like presbyopia and astigmatism. Alcon also provides viscoelastics, surgical solutions, surgical packs, and other disposable products for cataract and vitreoretinal surgery. In Ophthalmic Pharmaceuticals, the portfolio includes treatment options for elevated intraocular pressure caused by glaucoma, anti-infectives to aid in the treatment of bacterial infections and bacterial conjunctivitis, and ophthalmic solutions to treat inflammation and pain associated with ocular surgery, as well as an intravitreal injection for vitreomacular traction including macular hole. The Ophthalmic Pharmaceuticals portfolio also includes eye and nasal allergy treatments, as well as over-the-counter dry eye relief and ocular vitamins. The Vision Care portfolio comprises daily disposable, monthly replacement, and color-

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enhancing contact lenses, as well as a complete line of contact lens care products including multi-purpose and hydrogen-peroxide based solutions, rewetting drops and daily protein removers.

In 2014, Alcon accounted for $10.8 billion, or 19%, of Group net sales, and for $1.6 billion, or 14%, of Group operating income (excluding Corporate income and expense, net).

Sandoz Division

Our Sandoz Division focuses primarily on developing, manufacturing, distributing and selling prescription medicines that are not protected by valid and enforceable third-party patents, and pharmaceutical and biotechnological active substances. Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals & Oncology Injectables. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. Retail Generics includes the areas of Dermatology, Respiratory and Ophthalmics, as well as the specialty areas of cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies. In Anti-Infectives, Sandoz supplies generic antibiotics to a broad range of customers, as well as active pharmaceutical ingredients and intermediates to the pharmaceutical industry worldwide. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and provides biotechnology manufacturing services to other companies, and in Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

In 2014, Sandoz accounted for $9.6 billion, or 16%, of Group net sales, and for $1.1 billion, or 10%, of Group operating income (excluding Corporate income and expense, net).

Discontinuing Operations:

Vaccines Division

Our Vaccines Division researches, develops, manufactures, distributes and sells human vaccines worldwide. As previously announced, we have agreed to divest our Vaccines Division (excluding its influenza vaccines business) to GSK for up to $7.1 billion, consisting of $5.25 billion upfront and up to $1.8 billion in milestones, plus royalties. We expect that this transaction will close in the first half of 2015. This transaction is inter-conditional with the other announced transactions with GSK described under " Pharmaceuticals Division" and " Consumer Health." In October 2014, we announced that we had reached a definitive agreement with CSL to divest our Vaccines Division's influenza vaccines business for $275 million. We expect that this transaction will close in the second half of 2015. Prior to the January 9, 2014, completion of the divestment of our blood transfusion diagnostics unit to Grifols S.A. for approximately $1.7 billion in cash, the division was known as Vaccines and Diagnostics. Diagnostics researched, developed, distributed and sold blood testing products.

In 2014, the Vaccines Division accounted for $1.5 billion, or 3%, of Group net sales, and an operating loss of $0.6 billion.

Consumer Health

Following the January 1, 2015 completion of the divestment of our Animal Health Division to Lilly for approximately $5.4 billion, Consumer Health now consists of our OTC (Over-the-Counter) Division. Prior to the divestment of Animal Health to Lilly, each of OTC and Animal Health had its own research, development, manufacturing, distribution and selling capabilities, but neither was material enough to the Group to be separately disclosed as a segment. OTC offers readily available consumer medicines. Prior to its divestment, Animal Health provided veterinary products for farm and companion animals. As previously announced, we have agreed with GSK to create a joint venture in consumer health by combining our OTC Division with the GSK consumer healthcare business, of which we would own 36.5% and would have four of eleven seats on the joint venture's Board. We will also have customary minority

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rights and exit rights under a pre-defined, market-based pricing mechanism. We expect that this transaction will close in the first half of 2015. This transaction is inter-conditional with the other announced transactions with GSK described under " Pharmaceuticals Division" and " Vaccines Division."

In 2014, Consumer Health accounted for $4.3 billion, or 7%, of Group net sales, and for $0.5 billion, or 4%, of Group operating income (excluding Corporate income and expense, net).

PHARMACEUTICALS

Overview

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

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

Oncology

Cardio-Metabolic

Immunology and Dermatology

Retina

Respiratory

Neuroscience

Established Medicines

The Pharmaceuticals Division is organized into global business franchises responsible for the commercialization of various products. The preceding list reflects the new composition of therapeutic areas within our Pharmaceuticals Division following recent changes as part of a larger transformation of organizational structures. The following tables and product descriptions reflect this new organizational structure. Other sections of this Form 20-F, however, still reflect the prior composition of therapeutic areas. This includes the discussions and certain historical information provided in "Item 5. Operating and Financial Review and Prospects" and "Item 18. Financial Statements." In 2014, our Pharmaceuticals Division also created a unit focused on the development and commercialization of Cell and Gene Therapies.

On April 22, 2014, Novartis announced that it had reached definitive agreements with GSK on a set of inter-conditional transactions that, if completed, would impact our Pharmaceuticals Division. As part of these transactions, we have agreed to acquire GSK oncology products and certain related assets for an aggregate cash consideration of $16 billion. Up to $1.5 billion of this cash consideration is contingent on certain development milestones. In addition, under the terms of the agreement we were granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines. The right of first negotiation is for a period of twelve and one half years from the acquisition closing date. We expect these transactions to close during the first half of 2015. The proposed transactions with GSK are subject to closing conditions and regulatory approvals.

The Pharmaceuticals Division is the largest contributor among the divisions of Novartis and reported consolidated net sales of $31.8 billion in 2014, which represented 55% of the Group's net sales.

The division is made up of approximately 80 affiliated companies which together employed 59,079 full-time equivalent associates as of December 31, 2014 (including NIBR), and sell products in approximately 155 countries. The product portfolio of the Pharmaceuticals Division includes more than 50

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key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 134 potential new products and new indications or new formulations for existing products in various stages of clinical development.

Pharmaceuticals Division Products

The following table and summaries describe certain key marketed products in our Pharmaceuticals Division. While we intend to sell our marketed products throughout the world, not all products and indications are currently available in every country. Compounds and new indications in development are subject to required regulatory approvals and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. It may not be possible to obtain regulatory approval for any or all of the new compounds and new indications referred to in this Form 20-F in any country or in every country. In addition, for some of our products, we are required to conduct post-approval studies (Phase IIIb/IV) to evaluate long-term effects or to gather information on the use of the products under special conditions. See " Regulation" for further information on the approval process. Some of the products listed below have lost patent protection or are otherwise subject to generic competition. Others are subject to patent challenges by potential generic competitors. The dates described under "Patents and Exclusivity" are based on the expiration of relevant patent protection for the product (usually the active ingredient) or on the expiration of regulatory data protection (RDP) for the product. Please see " Intellectual Property" for general information on intellectual property and RDP, and for further information on the status of patents and exclusivity for Pharmaceuticals Division products.

Selected Marketed Products

Business franchise	**Product**	**Common name**	**Indications (vary by country and/or formulation)**	**Formulation**	**Patents and Exclusivity**
Oncology	*Afinitor* and *Afinitor Disperz/ Votubia*	everolimus	Advanced renal cell carcinoma after failure of treatment with VEGF-targeted therapy Advanced pancreatic neuroendocrine tumors SEGA associated with tuberous sclerosis Renal angiomyolipoma associated with tuberous sclerosis Advanced breast cancer in post-menopausal HR+/HER2 women in combination with exemestane, after failure of anastrozole or letrozole	Tablet Dispersible tablets for oral suspension	US 2020* EU 2018-19 Japan 2018
	Exjade	deferasirox	Chronic iron overload due to blood transfusions and non-transfusion dependent thalassemia	Dispersible tablet for oral suspension	US 2019* EU 2021 Japan 2021

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	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	US Expired* EU Expired Japan RDP 2015
	Gleevec/Glivec	imatinib mesylate / imatinib	Certain forms of Ph+ chronic myeloid leukemia Certain forms of KIT+ gastrointestinal stromal tumors Certain forms of acute lymphoblastic leukemia Dermatofibrosarcoma protuberans Hypereosinophilic syndrome Aggressive systemic mastocytosis Myelodysplastic/myeloproliferative diseases	Tablet Capsules	US July 2015* (including pediatric extension) EU (major countries) 2016 Japan expired for the main indications
	Jakavi	ruxolitnib	Disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis	Tablet	EU 2027* Japan 2027
	Sandostatin LAR and *Sandostatin* SC	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	US 2017* EU expired Japan expired
	Signifor and *Signifor* LAR	pasireotide	Cushing's disease Acromegaly	Solution for subcutaneous injection in Ampoule Powder and solvent for suspension for IM injection	US 2026 EU 2026 Japan 2026
	Tasigna	nilotinib	Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec* First line chronic myeloid leukemia	Capsule	US 2023 EU 2023 Japan 2024

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	Zometa	zoledronic acid	Skeletal-related events from bone metastases (cancer that has spread to the bones) Hypercalcemia of malignancy	Vial/4mg Ready-to-use	Active ingredient expired
	Zykadia	ceritinib	Anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC)	Capsules	US 2030 EU 2027 Japan 2027
Cardio-Metabolic	*Galvus* and *Eucreas*	*Galvus*: vildagliptin *Eucreas*: vildagliptin and metformin	Type 2 diabetes	Tablet	US not launched EU 2022* Japan 2024 Metformin active ingredient expired
Immunology and Dermatology	*Cosentyx*	secukinumab	Moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy Psoriasis vulgaris and psoriatic arthritis in adults who are not adequately responding to systemic therapies (except for biologics)	Lyophilized pre-filled syringe; Auto-injector	US 2028* EU 2030 Japan 2029
	Ilaris	canakinumab	Cryopyrin-associated periodic syndromes Systemic juvenile idiopathic arthritis Gouty arthritis (EU)	Lyophilized powder for reconstitution for subcutaneous injection	US 2024 EU 2024 (2025 provided pediatric extension granted) Japan 2024 (for CAPS)
	Myfortic	mycophenolic acid (as mycophenolate sodium)	Prophylaxis of organ rejection in patients receiving allogeneic renal transplants	Gastro-resistant tablet	Active ingredient expired*
	Neoral and *Sandimmune*	cyclosporine, USP Modified	Prevention of rejection following certain organ transplantation Non-transplantation autoimmune conditions such as severe psoriasis and severe rheumatoid arthritis	Capsule Oral solution Intravenous (*Sandimmune*)	Active ingredient expired

Simulect	basiliximab	Prevention of acute organ rejection in de novo renal transplantation	Vial for injection or infusion	US 2020 EU Expired Japan Expired
Xolair	omalizumab	Chronic Spontaneous Urticaria (CSU)/ Chronic idiopathic Urticaria See also, "Respiratory"	Lyophilized powder in vial and liquid formulation in pre-filled syringes	US 2018* EU 2017 Japan 2017
Zortress/Certican	everolimus	Prevention of organ rejection (heart, liver and kidney)	Tablet Dispersible tablet	US 2020* EU 2018-19 Japan 2018

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
Retina	*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 Visual impairment due to choroidal neovascularization secondary to pathologic myopia	Intravitreal injection	EU January 2022* Japan 2020
Respiratory	*Arcapta Neohaler/ Onbrez Breezhaler*	indacaterol	Chronic obstructive pulmonary disease	Inhalation powder hard capsules	US 2025* EU 2024 Japan 2025
	Seebri Breezhaler	glycopyrronium bromide	Chronic obstructive pulmonary disease	Inhalation powder hard capsules	Active ingredient: Expired* Formulations and uses: US 2025 EU 2025 Japan 2025 RDP: US 2018 EU 2022 Japan 2020
	TOBI and *TOBI Podhaler*	tobramycin	*Pseudomonas aeruginosa* infection in cystic fibrosis	Nebulizer solution (*TOBI*), Inhalation powder (*TOBI Podhaler*)	Active ingredient: Expired* Commercial product: US RDP for *TOBI Podhaler* 2016 EU orphan exclusivity for *TOBI Podhaler* until 2023
	Ultibro Breezhaler	indacaterol / glycopyrronium bromide	Chronic obstructive pulmonary disease	Inhalation powder hard capsules	US 2025* EU 2024
	Xolair	omalizumab	Severe allergic asthma See also, "Immunology and Dermatology"	Lyophilized powder in vial and liquid formulation in pre-filled syringes	US 2018 EU 2017 Japan 2017
Neuroscience	*Comtan*	entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet	Active ingredient: Expired Japan RDP 2017
	Exelon	*Rivastigmine*	Mild-to-moderate Alzheimer's disease dementia Severe Alzheimer's disease dementia Dementia associated with Parkinson's disease	Capsule Oral solution Transdermal patch	Active Ingredient: Expired* US: Data Protection until Aug 2015 for

	15cm^2 patch Formulation: US 2019 EU 2019 Japan 2023 (patent plus patent term extension) Japan: RDP May 2019

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	Extavia	interferon beta-1b	Relapsing remitting and/or relapsing forms of multiple sclerosis in adult patients	Subcutaneous injection	Active ingredient expired
	Gilenya	fingolimod	Relapsing forms of multiple sclerosis	Capsule	Active ingredient (including 5 year patent term extensions): US 2019* EU 2018 Japan 2018 RDP: EU 2021 Japan 2021
	Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet	Active ingredients: Expired* Combination patent: US 2020 EU 2020 Japan 2020
Established Medicines	*Amturnide*	aliskiren, amlodipine besylate and hydrochlorothiazide	Hypertension	Tablet	US 2018 (not including pediatric extension) EU 2020 (not including pediatric extension) Japan 2020
	Cibacen	benazepril hydrochloride	Hypertension Adjunct therapy in congestive heart failure Progressive chronic renal insufficiency	Tablet	No protection
	Clozaril/Leponex	clozapine	Treatment-resistant schizophrenia Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and psychotic disorders	Tablet	No protection
	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	Active ingredients: Expired US combination patent 2015
	Cubicin	daptomycin	Complicated skin and skin structure infections caused by Gram-positive susceptible isolates *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by susceptible isolates	Powder for solution for injection or infusion	EU RDP 2016*

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	Diovan	valsartan	Hypertension Heart failure Post-myocardial infarction	Tablets Capsules Oral solution	Active ingredient expired*
	Diovan HCT and *Co-Diovan*	valsartan and hydrochlorothiazide	Hypertension	Tablet	US expired* EU expired Japan 2016 (*Co-Diovan*)
	Exforge and *Exforge HCT*	valsartan and amlodipine besylate	Hypertension	Tablet	US expired* EU expired Japan 2015 (*Exforge* only) EU RDP 2017
	Focalin and *Focalin XR*	dexmethylphenidate HCl and dexmethylphenidate extended release	Attention deficit hyperactivity disorder	Tablet Capsule	Active ingredient: Expired Formulation: US 2018*
	Foradil	formoterol	Asthma Chronic obstructive pulmonary disease	*Aerolizer* (capsules) Aerosol	No protection
	Lamisil	terbinafine (terbinafine hydrochloride)	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* Onychomycosis of the toenail or fingernail due to dermatophytes	Tablet Cream DermGel Solution Spray	Active ingredients expired
	Lescol and *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 (*Lescol)* Tablet (*Lescol XL*)	Active ingredient expired
	Reclast/Aclasta	zoledronic acid 5 mg	Treatment of osteoporosis in postmenopausal women Treatment of osteoporosis in men Treatment and prevention of glucocorticoid-induced osteoporosis Prevention of postmenopausal osteoporosis Treatment of Paget's disease of the bone	Intravenous solution for infusion	Active ingredient: Expired Dosage regime: EU 2021
	Ritalin	methylphenidate HCl	Attention deficit hyperactivity disorder and narcolepsy	Tablet	Active ingredient expired*

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	Ritalin LA	methylphenidate HCl modified release	Attention deficit hyperactivity disorder	Capsule	Active ingredient expired*
	Tegretol	carbamazepine	Epilepsy Pain associated with trigeminal neuralgia Acute mania and bipolar affective disorders Alcohol withdrawal syndrome Painful diabetic neuropathy Diabetes insipidus centralis Polyuria and polydipsia of neurohormonal origin	Tablet Chewable tablet Oral suspension Suppository	Active ingredient expired
	Tekamlo and *Rasilamlo*	aliskiren and amlodipine besylate	Hypertension	Tablet	US 2018 (not including pediatric extension) EU 2020 (not including pediatric extension) Japan 2020
	Tekturna/Rasilez	aliskiren	Hypertension	Tablet	US 2018 (not including pediatric extension) EU 2020 (not including pediatric extension) Japan 2020
	Tekturna HCT/ Rasilez HCT	aliskiren and hydrochlorothiazide	Hypertension	Tablet	US 2018 (not including pediatric extension) EU 2020 (not including pediatric extension) Japan 2020
	Trileptal	oxcarbazepine	Epilepsy	Tablet Oral suspension	Active ingredient expired Oral formulation US 2020
	Tyzeka/Sebivo	telbivudine	Chronic hepatitis B	Tablet Oral solution	US expired EU RDP 2017
	Vivelle-Dot/ Estradot	estradiol hemihydrate	Estrogen replacement therapy for the treatment of the symptoms of natural or surgically induced menopause Prevention of postmenopausal osteoporosis	Transdermal patch	Active ingredient expired

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation	Patents and Exclusivity
	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 in gynecology Other painful and/or inflammatory conditions such as renal and biliary colic, migraine attacks and as adjuvant in severe ear, nose and throat infections	Tablet Capsule Oral drops / oral suspension Ampoule for injection Suppository Gel Powder for oral solution Transdermal patch	Active ingredient expired

* See " Intellectual Property" for further information on the patent and exclusivity status of these products.

Key Marketed Products

Oncology

Gleevec/Glivec (imatinib mesylate/imatinib) is a kinase inhibitor approved to treat patients with metastatic and/or unresectable KIT (CD117) positive (KIT+) gastrointestinal stromal tumors (GIST), as an adjuvant treatment for certain adult patients following resection of KIT+ GIST, and as a targeted therapy for Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). First launched in 2001, *Gleevec/Glivec* is available in more than 120 countries. *Gleevec/Glivec* is also approved in the US, EU and Japan to treat Ph+ acute lymphoblastic leukemia, a rapidly progressive form of leukemia. *Gleevec/Glivec* is also approved in the US and EU to treat dermatofibrosarcoma protuberans, a rare solid tumor; hypereosinophilic syndrome; myelodysplastic/myeloproliferative diseases and other rare blood disorders. In the US, *Gleevec* is also approved for aggressive systemic mastocytosis. *Gleevec/Glivec* has received approvals in 68 countries as a post-surgery (adjuvant setting) therapy for certain adult patients with KIT+ GIST. Following approval by the FDA in January 2013, the EMA approved *Gleevec/Glivec* in July 2013 for pediatric patients with newly diagnosed Ph+ acute lymphoblastic leukemia in combination with chemotherapy.

Sandostatin SC and *Sandostatin LAR* (octreotide acetate/octreotide acetate for injectable suspension) is a somatostatin analogue 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 50 countries for treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary tumor location. A total of 58 countries have also approved a new presentation of *Sandostatin LAR*, which includes a new diluent, safety needle and vial adapter, with additional filings underway. *Sandostatin* was first launched in 1988 and is approved in more than 100 countries.

Afinitor and *Afinitor Disperz/Votubia* (everolimus) is an oral inhibitor of the mTOR pathway. *Afinitor* is approved in more than 100 countries including the US, EU member states and Japan for advanced renal cell carcinoma following vascular endothelial growth factor-targeted therapy. *Afinitor* is also approved in more than 85 countries, including the US, EU and Japan for the treatment of advanced pancreatic neuroendocrine tumors. In addition, *Afinitor* is approved in more than 90 countries for advanced hormone receptor-positive, HER2-negative breast cancer

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(advanced HR+/HER2 breast cancer). Everolimus is also approved in more than 80 countries including in the US as *Afinitor* and in the EU as *Votubia* to treat patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) and in more than 70 countries for the treatment of adult patients with renal angiomyolipomas and TSC who do not require immediate surgery. The dispersible tablet for oral suspension formulation of the product is now approved in the TSC-SEGA population in the US and EU. Everolimus, the active ingredient in *Afinitor*, is also available under the trade names *Zortress/Certican* for use in transplantation in the US and EU, respectively, and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Tasigna (nilotinib) is a signal transduction inhibitor of the BCR-ABL tyrosine kinase. Since its launch in 2007, *Tasigna* has been approved in more than 110 countries to treat patients with Ph+ CML in the chronic and/or accelerated phase who are resistant or intolerant to existing treatment, including *Gleevec/Glivec*. It is also approved in more than 85 markets, including the US, EU member states, Switzerland and Japan, to treat newly diagnosed patients in the chronic phase. Results from the global, randomized Phase III trial called ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients), a head-to-head comparison against *Gleevec/Glivec,* showed that *Tasigna* produced faster and deeper responses than *Gleevec/Glivec* in adult patients with newly diagnosed Ph+ CML. The ENESTnd five-year follow-up continued to demonstrate higher rates of early and deeper sustained molecular response, including a reduced risk of progression in patients treated with *Tasigna* compared to *Gleevec/Glivec*. Data also indicated a trend for higher overall survival and event-free survival in patients treated with *Tasigna* compared to *Gleevec/Glivec*. In addition, ENESTcmr is the first randomized trial in patients with Ph+ CML to investigate the impact of switching adult patients with residual molecular disease to *Tasigna* after a minimum of two years on treatment with *Gleevec/Glivec.* Three-year results from the ENESTcmr trial showed that switching to *Tasigna* led to deeper molecular responses in these patients, further reducing their disease burden.

Exjade (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older. Patients with congenital and acquired chronic anemia, such as thalassemia, sickle cell disease and myelodysplastic syndromes, require transfusions, which puts them at risk of iron overload. *Exjade* was first approved in 2005 and is now approved in more than 100 countries, including the US, EU member states and Japan. *Exjade* is also approved in more than 70 countries, including the US and EU member states, for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia. Regulatory applications have been submitted in the US, Canada and other countries for a new film-coated tablet formulation.

Femara (letrozole) is a once-daily oral aromatase inhibitor for the treatment of early stage or advanced breast cancer in postmenopausal women. *Femara* was first launched in 1996 and is currently available in more than 90 countries. *Femara* is approved in the US, EU member states and other countries in the adjuvant, extended adjuvant and neo-adjuvant (pre-operative) 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 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.

Jakavi (ruxolitinib) is an oral inhibitor of the JAK1 and JAK2 tyrosine kinases. It is the first JAK inhibitor indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. *Jakavi* is currently approved in more than 65 countries, including EU member states, Japan, Canada, Australia, Mexico and Argentina. In three-year follow-up data

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from the COMFORT-I and COMFORT-II Phase III studies in myelofibrosis, *Jakavi* treatment reduced the risk of death and resulted in sustained reductions in spleen size increased spleen size being a hallmark of myelofibrosis while also improving quality of life. In three-year follow-up of the COMFORT-II study, patients treated with *Jakavi* demonstrated an overall survival advantage compared to patients receiving conventional therapy with a 52% reduction in risk of death observed in the *Jakavi* arm compared with conventional therapy. Regulatory applications have been submitted in the EU, Switzerland and Japan for *Jakavi* in polycythemia vera, and in January 2015 the CHMP adopted a positive opinion for *Jakavi* for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US. Ruxolitinib, marketed in the US as Jakafi® by Incyte Corporation, was approved by the FDA in December 2014 for the treatment of patients with polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea. Jakafi® is also approved by the FDA for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.

Zometa (zoledronic acid for injection/zoledronic acid 4 mg) is a leading treatment to reduce or delay skeletal-related events, including pathologic fracture, spinal cord compression, and/or requirement of radiation therapy or surgery to bone, in patients with bone metastases (cancer that has spread to the bones) from solid tumors and multiple myeloma. First approved in the US in 2001 for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of calcium), *Zometa* is approved in more than 100 countries for this indication as well as for the treatment of patients with multiple myeloma and patients with bone metastasis from solid malignancies, including prostate, breast and lung cancer. Zoledronic acid, the active ingredient in *Zometa*, is also available under the trade names *Reclast/Aclasta* for use in non-oncology indications. *Reclast/Aclasta*, first approved in the EU in 2005, is now approved in 107 countries for the treatment of osteoporosis in postmenopausal women, osteoporosis in men, Paget's disease of bone and prevention of clinical fractures after hip fracture and for the treatment and prevention of glucocorticoid-induced osteoporosis.

Zykadia (ceritinib) is an oral, selective inhibitor of ALK, an important therapeutic target in lung cancer. In April 2014, *Zykadia* was granted accelerated approval by the FDA for the treatment of patients with anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. *Zykadia* is one of the first medicines to be approved following FDA Breakthrough Therapy designation, which was received in March 2013 due to the significant results observed in the clinical trials and the serious and life-threatening nature of ALK+ NSCLC in patients progressing on or intolerant to crizotinib who have no other treatment option. Additional regulatory submissions for *Zykadia* in ALK+ NSCLC are underway worldwide, with an application currently filed in the EU and several countries within North America, South America, Central America and Asia.

Signifor (pasireotide) is a somatostatin analogue approved in more than 65 countries, including countries of the EU, Switzerland and the US, for the treatment of adults with Cushing's disease for whom pituitary surgery is not an option or has not been curative. In addition, in November 2014, the EMA approved *Signifor* in a new long-acting release formulation for once-monthly intramuscular injection to treat adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with a first-generation somatostatin analogue, following a positive opinion from the CHMP in September 2014. In December 2014, the FDA approved *Signifor* LAR (long-acting release) for injectable suspension, for intramuscular use, for the treatment of patients with acromegaly who have had inadequate response to surgery and/or for whom surgery is not an option.

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Cardio-Metabolic

Galvus (vildagliptin), an oral DPP-4 inhibitor, and *Eucreas*, a single-pill combination of vildagliptin and metformin, are indicated for the treatment of type 2 diabetes. The products were first approved in 2007. *Galvus* is currently approved in more than 120 countries, including EU member states, Japan and countries in Latin America and Asia-Pacific. *Eucreas* was the first single pill combining a DPP-4 inhibitor and metformin that was approved in Europe and under the trade name *Galvus Met* is currently approved in more than 100 countries. In 2012, *Galvus* received EU approval for expanded use as a second-line monotherapy for type 2 diabetes patients who cannot take metformin. In addition, in 2012, the European Commission approved the use of *Galvus* and *Eucreas* in combination with other diabetes treatments. The first new approval was for the use of vildagliptin in combination with insulin, with or without metformin, for patients with type 2 diabetes when diet, exercise and a stable dose of insulin do not result in glycemic control. The second approval was for the use of vildagliptin in triple combination with metformin and a sulphonylurea for the treatment of type 2 diabetes when diet and exercise plus dual therapy with these two agents do not provide adequate glycemic control. In 2013, a German agency, the Gemeinsamer Bundesausschuss (G-BA), initiated an analysis of the benefits of drugs approved prior to 2011. As part of that analysis the G-BA concluded that *Galvus* and *Eucreas* did not provide an added benefit over certain other medicines indicated for the treatment of that disease. As a result, we were unable to reach agreement with the head organization of the German statutory health insurance funds, GKV-Spitzenverband, on an acceptable price for *Galvus* and *Eucreas*, and in 2014 we stopped distribution of these products in Germany.

Immunology and Dermatology

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 more than 90 countries.

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.

Zortress/Certican (everolimus) is an oral inhibitor of the mTOR pathway, indicated to prevent organ rejection following solid organ transplantation. *Zortress/Certican* has been extensively studied as an immunosuppressant agent in solid organ transplantation with more than 10,000 transplant recipients enrolled in Novartis-sponsored clinical trials worldwide. Under the trade name *Certican*, it is approved in more than 90 countries to prevent organ rejection for renal and heart transplant patients, and in addition, in more than 70 countries worldwide to prevent organ rejection for liver transplant patients. In the US, under the trade name *Zortress*, the drug is approved for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant as well as for the prophylaxis of allograft rejection in adult liver transplant recipients. Everolimus is also available from Novartis in different dosage strengths and for different uses in non-transplant patient populations under the brand names *Afinitor, Afinitor Disperz* and *Votubia*. Everolimus is also exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Ilaris (canakinumab) is a human monoclonal antibody that selectively binds and neutralizes interleukin-1β (IL-1β), a pro-inflammatory cytokine. Since 2009, *Ilaris* has been approved in over 60 countries for the treatment of children and adults suffering from cryopyrin-associated periodic syndromes, a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional

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arthritis, deafness, and potentially life-threatening amyloidosis. In 2013, *Ilaris* was approved in the EU for the treatment of acute gouty arthritis in patients who cannot be managed with standard of care, and in the US, EU and other countries for the treatment of systemic juvenile idiopathic arthritis. *Ilaris* is also being developed for hereditary periodic fever syndromes.

Xolair (omalizumab) is currently approved in the EU, Switzerland and 35 other countries as a treatment for chronic spontaneous urticaria (CSU)/chronic idiopathic urticaria (CIU) including approvals in Europe as add-on therapy for the treatment of CSU in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment, and, in the US, for the treatment of adults and adolescents (12 years of age and above) with CIU who remain symptomatic despite H1 antihistamine treatment. See also, *Xolair* in "Respiratory" below. Novartis licensed *Xolair* from Genentech/Roche. We co-promote *Xolair* with Genentech/Roche in the US and share a portion of operating income, but we do not record any US sales. Novartis records all sales of *Xolair* outside the US. See "Item 18. Financial Statements Note 27" for further information.

Cosentyx (secukinumab) is a fully human IgG1 monoclonal antibody that selectively binds to and neutralizes interleukin 17A (IL-17A), a key pro-inflammatory cytokine. In December 2014, *Cosentyx* was approved in Japan for the treatment of both psoriasis vulgaris and psoriatic arthritis in adults who are not adequately responding to systemic therapies (except for biologics). This approval marked the first country approval for *Cosentyx* in the world and made it the first IL-17A inhibitor to receive regulatory approval in either of these indications in Japan. In January 2015, *Cosentyx* was approved in the EU as a first-line systemic treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy, and in the US for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. *Cosentyx* is also being developed for psoriatic arthritis and ankylosing spondylitis.

Retina

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors (VEGF). It is the only anti-VEGF therapy licensed in many countries for four ocular indications: wet age-related macular degeneration (wet AMD), visual impairment due to diabetic macular edema (DME), visual impairment due to macular edema secondary to branch and central retinal vein occlusion (BRVO and CRVO), and visual impairment due to choroidal neovascularization secondary to pathologic myopia (myopic CNV). *Lucentis* is approved in more than 100 countries to treat patients with wet AMD, for the treatment of visual impairment due to DME and macular edema secondary to RVO. Also, *Lucentis* is licensed in more than 70 countries for the treatment of visual impairment due to myopic CNV. Since its launch in 2007, there are more than 2.8 million patient-treatment years of exposure for *Lucentis.* We licensed *Lucentis* from Genentech for development and commercialization outside of the US. See "Item 18. Financial Statements Note 27" for further information.

Respiratory

Xolair (omalizumab) is the only humanized monoclonal antibody approved for the treatment of moderate to severe persistent allergic asthma in the US in adolescents (aged 12 and above) and adults. *Xolair* is approved in more than 90 countries, including the US since 2003 and the EU since 2005. It is approved for severe persistent allergic asthma in the EU in children (aged six and above), adolescents, and adults. A liquid formulation of *Xolair* in pre-filled syringes has been launched in most European countries. In Japan, *Xolair* was approved in January 2009 for the treatment of severe persistent allergic asthma in adults (aged 15 and older) and was approved in August 2013 in pediatric patients aged 6 years or older for the same indication. See also, *Xolair* in "Immunology and Dermatology" above.

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TOBI Podhaler (tobramycin inhalation powder) is an inhaled dry powder formulation of the antibiotic tobramycin, delivered using a simple and portable patient-friendly device that reduces administration time by 72% relative to *TOBI* (tobramycin nebulizer solution), with comparable efficacy and safety. *TOBI Podhaler* was approved by the FDA in March 2013 and has been approved in the EU since July 2011. It is approved in over 60 countries. It is indicated for the management of cystic fibrosis patients aged six years and older with *Pseudomonas aeruginosa* infection in their lungs, whose lung function is within a certain range.

Arcapta Neohaler/Onbrez Breezhaler (indacaterol) is a once-daily long-acting beta$_2$-adrenergic agonist (LABA) administered in a single-dose dry powder inhaler indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). Once-daily *Onbrez Breezhaler* was first approved in the EU in November 2009 at two dose strengths, 150 mcg and 300 mcg. It is now approved in over 100 countries worldwide. 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. It was the first inhaled COPD product available to patients to be delivered via the low resistance *Breezhaler* inhalation device.

Seebri Breezhaler (glycopyrronium bromide), a once-daily inhaled long-acting muscarinic antagonist (LAMA), received its first regulatory approvals in September 2012. *Seebri Breezhaler* 44 mcg inhalation powder, hard capsules received approval in the EU as a maintenance bronchodilator treatment to relieve symptoms for adult patients with COPD, and in Japan the MHLW approved *Seebri* (glycopyrronium) Inhalation Capsules 50 mcg administered through the *Breezhaler* device as an inhaled maintenance bronchodilator treatment for the relief of various symptoms due to airway obstructive disease in COPD (chronic bronchitis, emphysema). It is now approved in more than 80 countries worldwide outside the US. *Seebri Breezhaler* is the second inhaled COPD product available to patients to be delivered via the *Breezhaler* inhalation device. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

Ultibro Breezhaler (indacaterol/glycopyrronium bromide) is a once-daily inhaled fixed-dose combination of the LABA indacaterol and the LAMA glycopyrronium bromide. *Ultibro Breezhaler* (indacaterol 85 mcg/glycopyrronium 43 mcg), inhalation powder, hard capsules was approved in the EU in September 2013 as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD, and in Japan the MHLW approved *Ultibro* Inhalation Capsules (glycopyrronium 50 mcg/indacaterol 110 mcg), delivered through the *Breezhaler* inhalation device, for relief of various symptoms due to airway obstruction in COPD (chronic bronchitis, emphysema). *Ultibro Breezhaler* is the third inhaled COPD product available to patients to be delivered via the *Breezhaler* inhalation device. It is approved in over 50 countries outside the US and launched in over 25 countries (including the UK, Germany, Japan and Canada). Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

Neuroscience

Gilenya (fingolimod) is the first oral therapy approved to treat relapsing-remitting multiple sclerosis (RRMS) and the first in a new class of compounds called sphingosine 1-phosphate receptor modulators. In the US, *Gilenya* is indicated for relapsing forms of MS. In the EU, *Gilenya* is indicated for adult patients with high disease activity despite treatment with at least one disease modifying agent, or rapidly evolving severe relapsing-remitting MS. *Gilenya* is the only oral disease-modifying therapy (DMT) to impact the course of RRMS with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. As of November 2014, more than 114,000 patients have been treated in clinical trials and in a post-marketing setting and there are currently more than 195,000 patient

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years of exposure. *Gilenya* is currently approved in over 80 countries around the world. *Gilenya* is licensed from Mitsubishi Tanabe Pharma Corporation.

Exelon (rivastigmine tartrate) and *Exelon* Patch (rivastigmine transdermal system) are cholinesterase inhibitors indicated for the treatment of Alzheimer's disease (AD) dementia and Parkinson's disease (PD) dementia. They are the oral and transdermal formulations, respectively, of the cholinesterase inhibitor rivastigmine. *Exelon* capsules have been available since 1997 to treat mild to moderate AD dementia and are approved in more than 90 countries. In 2006, *Exelon* became the only cholinesterase inhibitor to be approved for mild to moderate PD dementia in addition to AD in both the US and EU. *Exelon* Patch was approved in 2007 in the US and EU and has been approved for the treatment of mild-to-moderate AD in more than 90 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. The once-daily *Exelon* Patch has shown comparable efficacy and superior tolerability to the highest recommended doses of *Exelon* capsules, with significant improvement in cognition and overall functioning compared to placebo. In June 2013, the FDA expanded the approved indication for *Exelon* Patch to also include the treatment of patients with severe Alzheimer's disease. In January 2013, European Marketing Authorization was obtained for the higher dose in mild-to-moderate AD.

Comtan (entacapone) and *Stalevo* (carbidopa, levodopa and entacapone) are indicated for the treatment of patients with Parkinson's disease who experience end of dose motor (or movement) fluctuations, known as "wearing off". *Comtan* was approved in Europe in 1998 and in the US in 1999 while *Stalevo* was approved in the US and EU in 2003. Both products are marketed in more than 50 countries by Novartis under a licensing agreement with Orion Corporation. *Stalevo* was approved in China in August 2012 and was approved in Japan in July 2014.

Established Medicines

Diovan (valsartan), together with *Diovan HCT/Co-Diovan* (valsartan and hydrochlorothiazide), is an angiotensin II receptor blocker (ARB) and is one of the top-selling branded anti-hypertensive medications worldwide (IMS MAT September 2014; 57 countries audited). *Diovan* is the only agent in its class approved to treat all of the following: high blood pressure (including children 6 to 18 years), high-risk heart attack survivors and patients with heart failure. First launched in 1996, *Diovan* is available in more than 120 countries for treating high blood pressure, in more than 90 countries for heart failure, and in more than 70 countries for heart attack survivors. First launched in 1997, *Diovan HCT/Co-Diovan* is approved in over 100 countries worldwide. In July 2008, the FDA approved *Diovan HCT* for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In 2009, *Co-Diovan* was approved for treatment of high blood pressure in Japan. In September 2010, all EU member states locally approved *Diovan* for use in children aged 6 to 18 years. In 2012, the Japanese MHLW approved *Diovan* for the treatment of pediatric hypertension in children age 6 years or older. This approval marks the first time an ARB has been approved for the treatment of pediatric hypertension in children age 6 years or older in Japan. *Diovan* is subject to generic competition in the US, EU and Japan. *Diovan HCT/Co-Diovan* is subject to generic competition in the US and EU.

Exforge (valsartan and amlodipine besylate) is a single-pill combination of the ARB *Diovan* and the calcium channel blocker amlodipine besylate. First approved for the treatment of high blood pressure in Switzerland in 2006, and in the US and EU in 2007, it is now available in more than 100 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, a calcium channel blocker and a diuretic (hydrochlorothiazide). *Exforge HCT* was approved in the EU and the US in 2009, and is now available in more than 60 countries.

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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 registered 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 Sandoz Division markets generic versions of the product, our Alcon Division markets *Voltaren* for ophthalmic indications, and 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. *Ritalin LA* and *Focalin XR* are additionally indicated for ADHD in adults. *Ritalin* is also indicated for narcolepsy. *Ritalin* was first marketed during the 1950s and is available in over 70 countries. *Ritalin LA* is available in over 30 countries. *Focalin* comprises the active d-isomer of methylphenidate and therefore requires half the dose of *Ritalin*. *Focalin* and *Focalin XR* are available in the US.

Tegretol (carbamazepine) is indicated for epilepsy (partial seizures, generalized tonic clonic and mixed forms of seizures), acute mania and maintenance treatment of bipolar disorders, alcohol withdrawal syndrome, trigeminal neuralgia, glossopharyngeal neuralgia, painful diabetic neuropathy, diabetes insipidus centralis and polyuria and polydipsia of neurohormonal origin. It is available in 129 countries. Generics represent approximately 50% of the carbamazepine market.

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 and tolerability as well as metabolic and pharmacologic properties of the compound.

Phase II: Clinical studies that are performed with patients who have the target disease, with the aim of continuing the Phase I safety assessment in a larger group, assessing the efficacy of the drug in the patient population, and determining the appropriate doses for further evaluation.

Phase III: Large-scale clinical studies with several hundred to several thousand patients, which are conducted to establish the safety and efficacy of the drug-specific indications for regulatory approval. Phase III trials may also be used to compare a new drug against a current standard of care to evaluate the overall benefit-risk relationship of the new medicine.

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

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The following table and paragraph summaries provide an overview of the key projects currently in the Confirmatory Development stage within our Pharmaceuticals Division, including projects seeking to develop potential uses of new molecular entities, as well as potential additional indications or new formulations for already marketed products. The year that each project entered the current phase of development disclosed below reflects the year in which the decision to enter the phase was made. This may be different from the year in which the first patient received the first treatment in the related clinical trial. A reference to a project being in registration means that an application has been filed with a health authority for marketing approval.

Selected Development Projects

Project/Product	**Common name**	**Mechanism of action**	**Potential indication/ Disease area**	**Business franchise**	**Formulation/ Route of administration**	**Year Project Entered Current Development Phase**	**Planned filing dates/Current phase**
ACZ885	canakinumab	Anti-interleukin-1β monoclonal antibody	Hereditary periodic fevers	Immunology and Dermatology	Subcutaneous injection	2013	2016/III
			Secondary prevention of cardiovascular events	Cardio-Metabolic		2011	2017/III
Afinitor/*Votubia* (RAD001)	everolimus	mTOR inhibitor	Non-functioning GI and lung neuroendocrine tumors	Oncology	Oral	2012	2015/III
			Tuberous sclerosis complex seizures			2013	2016/III
			Diffuse large B-cell lymphoma			2009	2018/III
BAF312	siponimod	Sphingosine-1-phosphate receptor modulator	Secondary progressive multiple sclerosis	Neuroscience	Oral	2012	≥2019/III
BCT197	TBD	Anti-inflammatory agent	Chronic obstructive pulmonary disease	Respiratory	Oral	2011	≥2019/II
BGJ398	TBD	Pan-FGF receptor kinase inhibitor	Solid tumors	Oncology	Oral	2012	≥2019/II
BGS649	TBD	Aromatase inhibitor	Obese hypogonadotropic hypogonadism	Cardio-Metabolic	Oral	2010	≥2019/II
BKM120	buparlisib	PI3K inhibitor	Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor resistant, mTOR inhibitor naïve	Oncology	Oral	2011	2015/III
			Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor resistant			2011	2016/III

			Solid tumors			2011	≥2019/I
BYL719	alpelisib	PI3K inhibitor	Solid tumors	Oncology	Oral	2010	≥2019/I
BYM338	bimagrumab	Inhibitor of activin receptor Type II	Sporadic inclusion body myositis	Neuroscience	Intravenous infusion	2013	2016/III
			Hip fracture	Neuroscience		2013	≥2019/II
			Sarcopenia	Neuroscience		2014	≥2019/II
CAD106	TBD	Beta-amyloid-protein therapy	Alzheimer's disease	Neuroscience	Intramuscular injection	2008	≥2019/II
CJM112	TBD	Anti-interleukin-17 monoclonal antibody	Immune disorders	Neuroscience	Subcutaneous injection	2013	≥2019/I

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Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
Cosentyx (AIN457)	secukinumab	Anti-interleukin-17 monoclonal antibody	Psoriatic arthritis	Immunology and Dermatology	Subcutaneous injection	2011	2015/III
			Ankylosing spondylitis			2011	2015/III
CTL019	tisagenlecleucel-T	CD19-targeted chimeric antigen receptor T-cell immunotherapy	Adult and pediatric acute lymphoblastic leukemia	Cell and Gene Therapies Unit	Intravenous	2012	2016/II
			Diffuse large B-cell lymphoma			2014	2017/II
EGF816	TBD	Epidermal growth factor receptor	Solid tumors	Oncology	Oral	2014	≥2019/I/II
Exjade film-coated tablet (FCT)	deferasirox	Iron chelator	Iron overload	Oncology	Oral film-coated tablet	2014	US (registration)
FCR001	TBD	Inducing stable donor chimerism and immunological tolerance	Renal transplant	Cell and Gene Therapies Unit	Infusion	2009	≥2019/II
Gilenya	fingolimod	Sphingosine-1-phosphate receptor modulator	Chronic inflammatory demyelinating polyradiculoneuropathy	Neuroscience	Oral	2012	2017/III
HSC835	TBD	Stem cell regeneration	Stem cell transplantation	Cell and Gene Therapies Unit	Infusion	2012	≥2019/II
INC280	capmatinib	cMET inhibitor	Non-small cell lung cancer	Oncology	Oral	2013	2018/II
Jakavi	ruxolitinib	Janus kinase inhibitor	Polycythemia vera	Oncology	Oral	2014	EU (registration)
KAE609	cipargamin	PfATP4 inhibitor	Malaria	Established Medicines	Oral	2012	2017/II
KAF156	TBD	TBD	Malaria	Established Medicines	Oral	2013	≥2019/II
LBH589	panobinostat	pan-deacetylase inhibitor (pan-DACi)	Relapsed or relapsed-and-refractory multiple myeloma	Oncology	Oral	2014	US/EU (registration)
LCI699	osilodrostat	Aldosterone synthase inhibitor	Cushing's disease	Oncology	Oral	2011	2017/III
LCQ908	pradigastat	Diacylglycerol acyl transferase-1 inhibitor	Familial chylomicronemia syndrome	Cardio-Metabolic	Oral	2012	2015/III
LCZ696	valsartan and sacubitril (as	Angiotensin receptor/neprilysin	Chronic heart failure with reduced ejection	Cardio-Metabolic	Oral	2014	US/EU (registration)

	sodium salt complex)	inhibitor	fraction				
			Chronic heart failure with preserved ejection fraction			2013	≥2019/III
LDE225	sonidegib	Smoothened receptor/ hedgehog signaling inhibitor	Advanced basal cell carcinoma	Immunology and Dermatology	Oral	2014	US/EU (registration)

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Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
LEE011	ribociclib	CDK4/6 Inhibitor	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women)	Oncology	Oral	2013	2016/III
			Hormone receptor-positive, HER2 negative advanced breast cancer (premenopausal women)			2014	2018/III
			Solid tumors			2011	2018/I
LGX818[(1)]	encorafenib	RAF inhibitor	Solid tumors	Oncology	Oral	2012	≥2019/II
LIK066	TBD	SGLT 1 / 2 inhibitor	Type 2 diabetes	Cardio-Metabolic	Oral	2011	≥2019/II
LJM716	TBD	HER3 inhibitor	Solid tumors	Oncology	Intravenous	2012	≥2019/I
Lucentis	ranibizumab	Anti-VEGF monoclonal antibody fragment	Choroidal neovascularization and macular edema secondary to conditions other than age-related macular degeneration, diabetic macular edema, retinal vein occlusion and pathologic myopia	Retina	Intravitreal injection	2013	2016/III
			Retinopathy of Prematurity (ROP)			2014	2018/III
MEK162[(2)]	binimetinib	MEK inhibitor	NRAS mutant melanoma	Oncology	Oral	2013	2016/III
			Low-grade serous ovarian cancer			2013	2016/III
			Solid tumors			2011	≥2019/II
MEK162[(2)] and LGX818[(1)]	binimetinib and encorafenib	MEK inhibitor and RAF inhibitor	BRAF mutant melanoma	Oncology	Oral	2013	2016/III
OAP030 (*Fovista*)	TBD	Aptamer anti-platelet-derived growth factor (PDGF)	Wet age-related macular degeneration	Retina	Solution	2013	2016/III

PKC412	midostaurin	Signal transduction inhibitor	Acute myeloid leukemia	Oncology	Oral	2008	2015/III
			Aggressive systemic mastocytosis			2008	2015/II
QAW039	fevipiprant	CRTH2 antagonist	Asthma	Respiratory	Oral	2010	≥2019/II
			Atopic dermatitis	Immunology and Dermatology		2013	≥2019/II
QAX576	TBD	Anti-interleukin-13 monoclonal antibody	Allergic diseases	Immunology and Dermatology; Respiratory	Subcutaneous injection	2013	≥2019/II
QGE031	TBD	High affinity anti-IgE monoclonal antibody	Asthma	Respiratory	Subcutaneous injection	2012	≥ 2019/II
RLX030	serelaxin	Recombinant form of human relaxin-2 hormone	Acute heart failure	Cardio-Metabolic	Intravenous infusion	2009	2016/III
Seebri (NVA237)	glycopyrronium bromide	Long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Respiratory	Inhalation	EU: 2012 US: 2014	EU (approved) US (registration)[(3)]
Signifor LAR (SOM230)	pasireotide	Somatostatin analogue	Cushing's disease	Oncology	Long-acting release/Intramuscular injection	2011	2016/III

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Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
Tasigna	nilotinib	BCR-ABL inhibitor	Chronic myeloid leukemia treatment-free remission	Oncology	Oral	2012	2016/II
Tekturna	aliskiren	Direct renin inhibitor	Reduction of cardiovascular death/hospitalizations in chronic heart failure	Established Medicines	Oral	2009	2016/III
Ultibro (QVA149)	indacaterol and glycopyrronium bromide	Long-acting beta$_2$-adrenergic agonist and long-acting muscarinic antagonist	Chronic obstructive pulmonary disease	Respiratory	Inhalation	EU: 2013 US: 2014	EU (approved) US (registration)[3]
Zykadia (LDK378)	ceritinib	ALK inhibitor	ALK+ advanced non-small cell lung cancer (post chemotherapy and post crizotinib)	Oncology	Oral	US: 2014 EU: 2014	US (approved) EU (registration)
			ALK+ advanced non-small cell lung cancer (chemotherapy naïve, crizotinib naïve)			2013	2017/III

(1) Conditional on completion of the previously announced transactions with GSK and receipt of regulatory approvals, we have agreed to divest LGX818 to Array BioPharma Inc.

(2) Conditional on completion of the previously announced transactions with GSK and receipt of regulatory approvals, we have agreed to return our rights in MEK162 to Array BioPharma Inc.

(3) Submission pending acceptance by FDA.

Key Development Projects

ACZ885 (canakinumab) was approved in the EU in March 2013 for the treatment of acute attacks in gouty arthritis as *Ilaris*. In 2013 *Ilaris* was also approved for the treatment of systemic juvenile idiopathic arthritis in the US, EU and other countries. Based on Phase II data of ACZ885 in TNF-receptor associated periodic syndrome and Familial Mediterranean Fever showing substantial symptom relief in these two rare periodic fever syndromes, a Phase III study was initiated in June 2014. The goal of this pivotal confirmatory study is to demonstrate efficacy and safety in TNF-receptor associated periodic syndrome, colchicine resistant Familial Mediterranean Fever and Hyper-IgD syndrome. This approach has been agreed with FDA and CHMP. ACZ885 is also being investigated in the pivotal Phase III CANTOS study to determine whether ACZ885 can reduce the risk of recurrent cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke) in post-myocardial infarction patients with elevated inflammatory burden versus placebo when administered quarterly in addition to standard of care.

Afinitor and *Afinitor Disperz/Votubia* (RAD001, everolimus) is an oral inhibitor of the mTOR pathway. Phase III studies are underway in patients with advanced breast cancer, diffuse large B-cell lymphoma and non-functioning GI/Lung NET. The EXIST-3 (EXamining everolimus In a Study of TSC) clinical trial is underway to evaluate the efficacy and safety of everolimus in patients with TSC who have refractory partial-onset seizures (uncontrollable seizures localized to a specific area of the brain). Results from the Phase III BOLERO-1 (Breast cancer trials of OraL EveROlimus-1) trial of everolimus in combination with trastuzumab and paclitaxel as a first-line treatment in women with human epidermal growth factor receptor-2 positive (HER2+) advanced breast cancer did not meet the threshold of statistical significance for both primary objectives of the study, progression-free survival among patients with HER2+ advanced breast cancer or the sub-population of women with hormone-receptor negative, HER2+ advanced breast cancer.

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BAF312 (siponimod) is an oral, second-generation sphingosine 1-phosphate receptor modulator in Phase III development for secondary progressive multiple sclerosis. BAF312 binds selectively to the sphingosine 1-phosphate receptor subtypes 1 and 5, distributes effectively to the brain where it may modulate central S1P1,5 receptors to impact central nervous system inflammation and repair mechanisms. The results from the BOLD study, an adaptive dose-ranging Phase II study, were published in *Lancet Neurology* in 2013. These results showed that compared to placebo, BAF312 reduced brain MRI lesions by up to 80% in relapsing-remitting multiple sclerosis and relapses were infrequent and significantly reduced. BAF312 entered Phase III development in secondary progressive multiple sclerosis in 2012.

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

BYM338 (bimagrumab) is a novel, fully human monoclonal antibody under development to treat sporadic inclusion body myositis (sIBM). In August 2013, FDA granted Breakthrough Therapy designation to BYM338 for sIBM. A Phase II/III study of bimagrumab in patients with sIBM was initiated in September 2013. This study showed that in sIBM patients, a single dose of bimagrumab improved muscle volume in eight weeks (muscle volume for right leg increased 6.5% compared to placebo) and muscle function by 16 weeks. BYM338 binds with high affinity to type II activin receptors, preventing natural ligands, including myostatin and activin, from binding. BYM338 stimulates muscle growth by blocking signaling from these inhibitory molecules. In addition to sIBM, BYM338 is in clinical development for multiple pathological muscle loss and weakness and muscle-wasting conditions, including recovery from hip fracture. BYM338 was developed by Novartis, in collaboration with MorphoSys.

Cosentyx (AIN457, secukinumab) is a fully human IgG1 monoclonal antibody that selectively binds to and neutralizes IL-17A, a key pro-inflammatory cytokine. In September 2014 Novartis announced that two Phase III studies in psoriatic arthritis (FUTURE 1 and FUTURE 2) met primary and key secondary endpoints showing superiority to placebo. FUTURE 1 and FUTURE 2 enrolled a combined total of more than 1,000 patients.

CTL019 (tisagenlecleucel-T) is an investigational therapy that uses chimeric antigen receptors (CARs) to fight cancer. CARs are engineered proteins that transform a patient's own T cells into antigen-specific cells which seek out target proteins present on a patient's cancerous tumor. When these cells are re-introduced into the patient's blood, they demonstrate the potential to bind to the cancer cells and destroy them. CTL019 targets a protein called CD19 that is associated with a number of B-cell malignancies. On-going Phase I and II studies being conducted by the University of Pennsylvania are investigating the activity and safety of CTL019 in patients with resistant or refractory CD19+ hematologic malignancies, specifically acute lymphoblastic leukemia, chronic lymphocytic leukemia and non-Hodgkin lymphoma. In one long-term pediatric study, results showed that 36 of 39 patients with relapsed/refractory acute lymphoblastic leukemia (r/r ALL), or 92%, experienced complete remissions with CTL019. Sustained remissions were achieved up to one year or more with six-month event-free survival of 70% and overall survival of 75%, in most cases without further therapy. All pediatric patients who responded to the therapy experienced a cytokine release syndrome, while their reprogrammed T-cells were expanding. Additional abstracts

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evaluated the efficacy and safety of CTL019 in the treatment of B-cell cancers including r/r ALL, chronic lymphocytic leukemia, and B-cell non-Hodgkin lymphoma.

Gilenya (fingolimod) is a sphingosine 1-phosphate receptor modulator approved for the treatment for relapsing remitting MS. A Phase III study of *Gilenya* in patients with chronic inflammatory demyelinating polyradiculoneuropathy was initiated in 2012. Submissions to health authorities in this indication are anticipated to be made in 2017. Results from INFORMS, the Phase III study of *Gilenya* in primary progressive MS did not show a significant difference between fingolimod and placebo on a combination of disability measures.

Jakavi (ruxolitinib) is an oral inhibitor of the JAK1 and JAK2 tyrosine kinases in development for use in patients with polycythemia vera. The pivotal Phase III RESPONSE study of ruxolitinib in patients with polycythemia vera who are resistant to or intolerant of hydroxyurea was presented at a major US medical congress in 2014. In the study, ruxolitinib significantly improved hematocrit control without the need for phlebotomy and reduced spleen size in patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. These data form the basis for worldwide regulatory filings for ruxolitinib in polycythemia vera. An update involving more than 1,000 patients from the Phase IIIb JUMP study, the largest clinical trial of myelofibrosis patients treated with ruxolitinib to date, was presented at a major US medical congress in 2014. Findings of this ongoing expanded access study support the safety profile and efficacy benefit of ruxolitinib, as measured in primary and secondary endpoints respectively. In the study, 69% of patients treated with ruxolitinib achieved a greater than or equal to 50% reduction in spleen length from baseline at any time and had a clinically meaningful improvement in myelofibrosis symptom score, important treatment goals for patients with myelofibrosis.

LBH589 (panobinostat) is a potent pan-deacetylase inhibitor under FDA review for the treatment of patients with relapsed or relapsed and refractory multiple myeloma. In November, the FDA extended its review period by up to three months for the NDA of LBH589 in combination with bortezomib and dexamethasone for patients with previously treated multiple myeloma. The extension followed an FDA Oncologic Drugs Advisory Committee (ODAC) meeting in November, at which ODAC voted against recommending LBH589 for this indication. Results from the PANORAMA-1 (PANobinostat ORAl in Multiple MyelomA) Phase III trial, which were presented at a major US medical congress, showed a 37% improvement in progression-free survival when using panobinostat in combination with bortezomib and dexamethasone compared to treatment with the same regimen with placebo in patients with relapsed or relapsed and refractory multiple myeloma. Worldwide regulatory filings are underway, including filings in the EU in May and in Japan, with orphan drug status, in September.

LCQ908 (pradigastat) is a diacylglycerol acyltransferase-1 (DGAT-1) inhibitor that blocks the final step of triglyceride synthesis in the small intestine, slowing and decreasing absorption of dietary fat. LCQ908 is currently in Phase III development for familial chylomicronemia syndrome, a rare genetic disease in which individuals lack an enzyme that clears triglycerides from the blood. The loss of this enzyme activity leads to very high triglycerides, which can lead to recurrent episodes of a potentially life-threatening condition called pancreatitis.

LCZ696 (valsartan and sacubitril, as sodium salt complex) is a first-in-class angiotensin receptor/neprilysin inhibitor in development for the treatment of chronic heart failure. LCZ696 acts to enhance the protective neurohormonal systems of the heart (neprilysin system) while simultaneously suppressing the harmful system (the renin-angiotensin-aldosterone system, or RAAS). In March 2014 the Phase III PARADIGM-HF study of LCZ696 in patients with chronic heart failure with reduced ejection fraction was stopped early when it was confirmed that those given LCZ696 were significantly less likely to die from cardiovascular causes then those given enalapril. Results presented at a major European medical congress in August 2014 showed LCZ696 reduced the risk of death from cardiovascular causes by 20%, reduced heart failure hospitalizations

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by 21% and the risk of all-cause mortality by 16%. Overall there was a 20% risk reduction on the primary endpoint, a composite measure of cardiovascular death or heart failure hospitalization. Based on these findings, regulatory applications have been submitted in both the EU and US for LCZ696 as a treatment for patients with heart failure with reduced ejection fraction. PARAGON-HF, a Phase III trial of LCZ696 in patients with chronic heart failure with preserved ejection fraction is underway.

LDE225 (sonidegib) is a selective smoothened inhibitor in clinical development for advanced basal cell carcinoma. LDE225 binds to smoothened receptors and prevents abnormal activation of the Hedgehog pathway, which is associated with uncontrolled cellular growth and proliferation. LDE225 was submitted in the EU in the second quarter of 2014 and in the US in the third quarter of 2014.

LEE011 (ribociclib) is an orally bioavailable, highly selective small molecule inhibitor of cyclin dependent kinase (CDK) 4 and 6. LEE011 may be able to stop the proliferation of growth factors in tumors where the CDK4/6 pathway has been activated and unchecked cell proliferation has occurred. The compound is in Phase III registration studies in hormone receptor-positive advanced breast cancer. LEE011 is also in Phase I and II investigation, with a number of ongoing studies in adult and pediatric solid tumors.

Lucentis (ranibizumab) is an anti-VEGF monoclonal antibody fragment in Phase III development for the treatment of visual impairment due to choroidal neovascularization and macular edema secondary to conditions other than age-related macular degeneration, diabetic macular edema, branch and central retinal vein occlusion and pathologic myopia. Filings are expected in 2016.

OAP030 (*Fovista*) is an oligo-nucleotide aptamer that inhibits the action of platelet-derived growth factor (PDGF), and has the potential to enhance the symptomatic treatment effect of anti-VEGFs to induce lesion regression, which may result in vision gains, reduce vision loss and potentially modify the disease in the longer term. The OAP030 Phase III program consists of three clinical trials to evaluate the safety and efficacy of OAP030 in combination with anti-VEGF drugs for the treatment of wet age-related macular degeneration (AMD). Initial top-line data from the OAP030 Phase III clinical program are expected to be available in 2016.

PKC412 (midostaurin) is an oral, multi-targeted kinase inhibitor in Phase III development for treatment of patients with FLT3-mutated acute myeloid leukemia (AML) and in Phase II development for aggressive systemic mastocytosis (ASM). Filings are expected for newly diagnosed, FLT3-mutated AML and for ASM in 2015.

RLX030 (serelaxin), the first in a new class of medicines, is a recombinant form of the human hormone relaxin-2, and is believed to act through multiple mechanisms on the heart, kidneys and blood vessels. Results from the Phase III RELAX-AHF study show that RLX030 improved symptoms and reduced mortality in patients with acute heart failure (AHF). Data from the study were presented at the American Heart Association congress in November 2012 and published simultaneously in *The Lancet* showing that RLX030 significantly reduced dyspnea (or shortness of breath), the most common symptom of AHF, which was the primary objective of the study based on pre-specified protocol criteria. In addition, RLX030 was associated with reductions in worsening of heart failure and all-cause mortality (a safety endpoint) and in deaths due to cardiovascular causes (an additional pre-specified exploratory endpoint) at the end of six months. In 2014, the FDA and CHMP each decided that further data would be required in order for marketing authorizations to be granted. A second Phase III study, RELAX-AHF-2, is underway and aims to replicate the key findings of RELAX-AHF, with cardiovascular mortality as the primary endpoint. RLX030 received regulatory approval from the Ministry of Health in Russia in 2014 and is launched there under the trade name *Reasanz*.

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Seebri (NVA237, glycopyrronium bromide) is an inhaled long-acting muscarinic antagonist. In January 2015, Novartis announced positive top-line results from the pivotal Phase III clinical trial programs for NVA237 to support an NDA submission to FDA for the long-term maintenance treatment of chronic obstructive pulmonary disease (COPD). The results from the Phase III GEM clinical trial program in moderate-to-severe COPD patients met their primary and secondary endpoints.

Signifor LAR (SOM230, pasireotide) is a somatostatin analogue in development as a long-acting release formulation for patients with Cushing's disease, with a Phase III study underway.

Tasigna (nilotinib) is a selective tyrosine-kinase inhibitor that inhibits the BCR-ABL protein produced by the Philadelphia chromosome, which is found in most people who have chronic myeloid leukemia (CML). Novartis has initiated a global clinical trial program to evaluate the potential for Philadelphia chromosome positive (Ph+) CML patients to maintain deep molecular response after stopping nilotinib. ENESTfreedom, ENESTop, ENESTgoal, and ENESTpath will evaluate the feasibility of stopping treatment, and achieving successful treatment free remission in patients with Ph+ CML in the chronic phase and deep molecular response on nilotinib. ENESTfreedom and ENESTop are pivotal trials and have completed enrollment. Six-year results from the ongoing randomized Phase III ENESTnd study demonstrate that *Tasigna* is superior to *Gleevec/Glivec* at achieving higher rates of early, deep and sustained molecular responses in newly-diagnosed patients with Philadelphia chromosome-positive chronic myeloid leukemia.

Ultibro (QVA149, indacaterol and glycopyrronium bromide) is an inhaled fixed-dose combination of the long-acting $beta_2$-adrenergic agonist indacaterol and the long-acting muscarinic antagonist glycopyrronium bromide. In January 2015, Novartis announced positive top-line results from the pivotal Phase III clinical trial programs for QVA149 to support an NDA submission to the FDA for the long-term maintenance treatment of COPD. The results from the Phase III EXPEDITION clinical trial program in moderate-to-severe COPD patients met their primary and secondary endpoints.

Zykadia (LDK378, ceritinib) is a potent and highly selective oral anaplastic lymphoma kinase (ALK) inhibitor that is in development for ALK positive (ALK+) cancers. Several major studies evaluating treatment with ceritinib are being conducted in more than 300 study centers across more than 30 countries. Two Phase II single-arm clinical trials in previously treated and treatment-naïve ALK+ non-small cell lung cancer (NSCLC) patients are fully enrolled and ongoing. In addition, two Phase III clinical trials comparing ceritinib with chemotherapy in treatment-naïve and in previously-treated NSCLC patients are ongoing and actively recruiting patients worldwide.

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Projects Added To And Subtracted From The Development Table Since 2013

Project/Product	Potential indication/ Disease area	Change	Reason
ACZ885	Gouty arthritis	Commercialized (EU) Terminated (US)	US development discontinued
Afinitor/*Votubia* (RAD001)	HER2+ breast cancer, 1st line	Terminated	Development discontinued
	HER2+ breast cancer, 2nd/3rd line	Terminated	Development discontinued
AFQ056	Fragile X syndrome	Terminated	Development discontinued
Cosentyx (AIN457)	Psoriasis	Commercialized	
	Rheumatoid arthritis	Terminated	Development discontinued
	Uveitis	Terminated	Development discontinued
AUY922	Solid tumors	Terminated	Development discontinued
BKM120	Breast cancer	Now disclosed as metastatic breast cancer, hormone receptor-positive, aromatase inhibitor resistant, mTOR inhibitor naïve; and metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor resistant	
BYM338	Sarcopenia	Added	Entered Confirmatory Development
CJM112	Immune disorders	Added	Entered Confirmatory Development
CTL019	Leukemia	Now disclosed as adult and pediatric acute lymphoblastic leukemia	
	Diffuse large B-cell lymphoma	Added	Entered Confirmatory Development
DEB025	Chronic hepatitis C	Removed	Hepatitis C virus strategy review

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Project/Product	Potential indication/ Disease area	Change	Reason
EGF816	Solid tumors	Added	Entered Confirmatory Development
Exjade film-coated tablet	Iron overload	Added	In registration in US
FCR001	Renal transplant	Added	Entered Confirmatory Development
Gilenya	Primary progressive multiple sclerosis	Terminated	Development discontinued
INC280	Non-small cell lung cancer	Added	Entered Confirmatory Development
KAF156	Malaria	Added	Entered Confirmatory Development
LBH589	Hematological cancers	Terminated	Development discontinued
LCZ696	Hypertension	Removed	Activities for submission on hold
LDE225	Medulloblastoma	Removed	No filing planned
	Solid tumors	Removed	No filing planned
LEE011	Breast cancer	Now disclosed as hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women) and hormone receptor-positive, HER2 negative advanced breast cancer (premenopausal women)	
LFF571	*Clostridium difficile* infection	Terminated	Development discontinued
LGX818	BRAF mutant melanoma	Terminated	Development discontinued in BRAF mutant melanoma as a single agent

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Project/Product	Potential indication/ Disease area	Change	Reason
Lucentis	Choroidal neovascularization and macular edema	Now disclosed as choroidal neovascularization and macular edema secondary to conditions other than age-related macular degeneration, diabetic macular edema, retinal vein occlusion and pathologic myopia	
	Retinopathy of Prematurity (ROP)	Added	Entered Confirmatory Development
OAP030 (*Fovista*)	Wet age-related macular degeneration	Added	Entered confirmatory development; licensing and commercialization agreement with Ophthotech signed May 2014
QAW039	Atopic dermatitis	Added	Entered Confirmatory Development
QGE031	Allergic diseases	Now disclosed as asthma	
Seebri (NVA237)	Asthma	Terminated	Development discontinued
Signifor LAR (SOM230)	Acromegaly	Commercialized	
TKI258	Solid tumors	Terminated	Development discontinued
Xolair	Chronic idiopathic urticaria/ Chronic spontaneous urticaria	Commercialized	

Principal Markets

The Pharmaceuticals Division sells products in approximately 155 countries worldwide. Net sales are generally concentrated in the US, Europe and Japan, which together accounted for 75% of the division's 2014 net sales. However, sales from expanding "emerging growth markets" have become increasingly important to us. See "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Factors Affecting Results of Operations Transformational Changes Fueling Demand Global Rise in

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Healthcare Spending." The following table sets forth the aggregate 2014 net sales of the Pharmaceuticals Division by region:

	2014 Net sales to third parties	
Pharmaceuticals		
	$ millions	**%**
Europe	11,245	35
United States	9,772	31
Asia, Africa, Australasia	7,655	24
Canada and Latin America	3,119	10
Total	**31,791**	**100**

	$ millions	**%**
Established Markets*	23,653	74
Emerging Growth Markets*	8,138	26
Total	**31,791**	**100**

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

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

Production

The primary goal of our manufacturing and supply chain management program is to ensure the uninterrupted, timely and cost-effective supply of products that meet all product specifications. We manufacture our products at five bulk chemical and 14 pharmaceutical production facilities as well as one biotechnology site. 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. We have a biotechnology plant located in Huningue, France, and another biotechnology plant is under development in Morris Plains, New Jersey to manufacture personalized medicine. Our biotechnology site in Basel, Switzerland was closed in 2014, and our biotechnology site in Vacaville, California was transferred to Novartis Animal Health in October 2014. In January 2014, we announced the closing of the production facility located in Suffern, New York. In addition, in 2014 we announced the planned divestment of our pharmaceutical manufacturing site in Taboão da Serra, Brazil.

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, we maintain multiple supply sources so that the business

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

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

Marketing and Sales

The Pharmaceuticals Division serves customers with 1,940 field force representatives in the US, and an additional 20,643 in the rest of the world, as of December 31, 2014, including supervisors and administrative personnel. 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.

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

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

The marketplace for healthcare is evolving with consumers becoming more informed stakeholders 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.

As a result of changes in healthcare economics, managed care organizations are now one of the largest groups 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 team that actively seeks to optimize formulary positions for our products.

Competition

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

In addition, as is the case with other pharmaceutical companies selling patented pharmaceuticals, Novartis faces ever-increasing challenges from companies selling products which compete with our products, including competing patented products and generic forms of our products following the expiry of patent protection. Generic companies may also gain entry to the market through successfully challenging our patents, but we vigorously use legally permissible measures to defend our patent rights. 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 a leader in the pharmaceuticals industry in terms of research and development, including the level of our investment. Our Pharmaceuticals Division invested the following in research and development over the last three years:

	2014		2013		2012	
	$ millions	Core R&D[1] $ millions	$ millions	Core R&D[1] $ millions	$ millions	Core R&D[1] $ millions
Research and Exploratory Development	2,724	2,654	2,664	2,611	2,584	2,530
Confirmatory Development	4,607	4,343	4,578	4,550	4,334	4,167
Total	**7,331**	**6,997**	**7,242**	**7,161**	**6,918**	**6,697**

(1) Core excludes impairments, amortization and certain exceptional items

Our Pharmaceuticals Division expensed $7.3 billion (on a core basis $7.0 billion) in research and development in 2014. This represented 23% (on a core basis 22%) of the division's total net sales.

Research and Exploratory Development expenditure was $2.7 billion in 2014, in line with the Research and Exploratory Development expenditure of $2.7 billion in 2013 and the 2012 amount of $2.6 billion.

Confirmatory Development expenditures in 2014 were $4.6 billion, in line with 2013. This included $289 million in impairments of intangible assets in 2014 (2013: $29 million). On a core basis, Confirmatory Development expenditures decreased to $4.3 billion in 2014 and represented 14% of our Pharmaceuticals Division's net sales.

Confirmatory Development expenditures in 2013 increased by 6% to $4.6 billion as compared against 2012. This included $29 million in impairments of intangible assets in 2013 (2012: $0.1 billion). On a core basis, Confirmatory Development expenditures increased to $4.6 billion in 2013 (2012: $4.2 billion) and represented 14% of our Pharmaceuticals Division's net sales.

The discovery and development of a new drug is a lengthy process, usually requiring approximately 10 to 15 years from the initial research to bringing a drug to market, including approximately six to eight years from Phase I clinical trials to market entry. 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 strategic 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. The principal goal of our research program is to discover new medicines for diseases with unmet medical need. To do this we focus our work in areas where we have sufficient scientific understanding and believe we have the potential to change the practice of medicine. This requires the hiring and retention of the best talent, a focus on fundamental disease mechanisms that are relevant across different disease areas, continuous improvement in technologies for drug discovery and potential therapies, close alliance with clinical colleagues, and the establishment of appropriate external complementary alliances.

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

In 2003, we established the Novartis Institutes for BioMedical Research (NIBR). At NIBR's headquarters in Cambridge, Massachusetts, more than 1,900 scientists, physicians and business professionals contribute to research into disease areas such as cardiovascular and metabolism disease, neuroscience, oncology, muscle disorders and ophthalmology. Additionally, more than 4,300 scientists, physicians and business professionals contribute to research in Switzerland, Italy, Singapore, China and three other US sites. Research is conducted at these sites in areas including neuroscience, autoimmune diseases, oncology, cardiovascular and metabolism diseases, and gastrointestinal diseases. Research platforms such as the Center for Proteomic Chemistry are headquartered at the NIBR site in Basel, Switzerland. In addition, the Novartis Institute for Tropical Diseases, Novartis Vaccines for Global Health, the Friedrich 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, dengue and African sleeping sickness.

In August 2012, Novartis and the University of Pennsylvania (Penn) announced an exclusive global research and development collaboration to develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies for the treatment of cancers. The research component of this collaboration focuses on accelerating the discovery and development of additional therapies using CAR immunotherapy. In September, as part of its alliance with Novartis, Penn announced plans for the construction of a Center for Advanced Cellular Therapeutics (CACT) on the Penn Medical School campus in Philadelphia. The CACT is planned to be a first of its kind research and development center established specifically to develop and manufacture adoptive T cell immunotherapies under the research collaboration guided by scientists and clinicians from NIBR and Penn. Construction of the CACT is expected to be completed in 2016.

In April 2013, we announced that ophthalmic pharmaceuticals research would be consolidated in Cambridge, Massachusetts. Previously this research was conducted at two sites on the Alcon campus in Fort Worth, Texas, and in Cambridge, Massachusetts. This consolidation is part of our ongoing effort to co-locate teams and pursue new scientific directions.

In August 2013, we announced that we will build a neuroscience research team in Cambridge. This new group will focus on using stem cell models, human genetics, and other fields to discover new medicines for psychiatric and neurodegenerative diseases.

In November 2013, we took action to co-locate scientific resources in order to improve the efficiency and effectiveness of our global research organization. We announced that we will establish a respiratory research group at our site in Cambridge, Massachusetts, and a proposal to close the Horsham, UK research site, as well as a plan to exit research in topical applications for dermatology and exit from the Vienna, Austria research site. After the consultation period with local works councils in the UK and Austria, these proposals were confirmed and both sites were closed in 2014. In addition, we announced the consolidation of US-based oncology research from Emeryville, California to Cambridge, Massachusetts and the closing of the biotherapeutics development unit in La Jolla, California.

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In February 2014 we acquired CoStim Pharmaceuticals Inc., a Cambridge, Massachusetts-based, privately held biotechnology company focused on harnessing the immune system to eliminate immune-blocking signals from cancer. This acquisition enhanced our late discovery stage immunotherapy programs directed to several targets, including PD-1.

Development program

The focus of our Development program is to determine the safety and efficacy of a potential new medicine in humans. As previously described (see " Compounds in Development"), we view the development process as generally consisting of an Exploratory phase where "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 efficacy and safety, and to establish the appropriate therapeutic dose. In Phase III clinical trials, the drug is further tested in larger numbers of volunteer patients in clinics and hospitals. In each of these phases, physicians monitor volunteer patients closely to assess the potential new 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 regulatory application to the health authorities. The IMB is also responsible for project discontinuations, for the endorsement of overall development strategy and the endorsement of development project priorities. The IMB is chaired by the Head of Development of our Pharmaceuticals Division and has representatives from Novartis senior management, as well as experts from a variety of fields among its core members and extended membership.

Cell and Gene Therapies Unit

Novartis Pharmaceuticals has created a dedicated unit focused on the development and commercialization of Cell and Gene Therapies. The Cell and Gene Therapies Unit aims to develop a new approach to treating or potentially curing some patients suffering from a variety of life-threatening diseases, including blood-borne cancers, sickle cell disease, thalassemias and other diseases of the blood by replacing, repopulating or resetting the immune system. The unit will initially focus on novel cell therapies and cell-based gene therapies including: Chimeric Antigen Receptor Technology (CART) in immuno-oncotherapy with CTL019, Facilitated Cell Therapy Platform (FCRx) in renal transplantation with FCR001 and stem cell expansion and transplantation with HSC835.

Diagnostics

Recent advances in biology and bioinformatics have led to a much deeper understanding of the underlying genetic drivers of disease and the molecular pathways cancer uses to progress. Novartis is developing new therapies that specifically target the mechanisms responsible for disease. To support these advances, Novartis is developing innovative diagnostic tests that could potentially improve physicians' ability to administer the appropriate treatment to those patients who have the greatest potential to benefit from them. Our Pharmaceuticals Division has two units that support our commitment to advancing precision medicine.

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Companion Diagnostics

Our Companion Diagnostics (CDx) function works as an integrated part of the drug development process. CDx brings internal capabilities and resources to bear in the development of new diagnostic tests to support our global program teams and efforts in various disease areas. Additionally, the CDx team forms strategic collaborations with third parties to secure access to technologies and capabilities that fit the requirements of our drug development programs. The CDx unit develops tests to meet high regulatory standards for the approval of companion diagnostics around the world.

Genoptix Medical Laboratory

In 2011, Novartis acquired Genoptix Medical Laboratory, located in Carlsbad, California. This organization provides comprehensive diagnostics and informatics services to community-based hematologists and oncologists in the US. As one of the largest hematopathology centers in the US, Genoptix offers comprehensive testing solutions in hematology and solid tumor molecular profiling. Their mission is to create value for the patient and the healthcare system by transforming diagnostic information into actionable clinical insights. Genoptix also provides services to support Novartis and third-party clinical trials.

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

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

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

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

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

United States

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

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

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

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

European Union

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

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Under the Centralized Procedure, applications are made to the EMA for an authorization which is valid for the European Community. The Centralized Procedure is mandatory for all biotechnology products and for new chemical entities in cancer, neurodegenerative disorders, diabetes and AIDS, autoimmune diseases or other immune dysfunctions and optional for other new chemical entities or innovative medicinal products or in the interest of public health. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's quality, safety and efficacy, then the company may submit an application to the EMA. The EMA then receives and validates the application, and appoints a Rapporteur and Co-Rapporteur to review it. The entire review cycle must be completed within 210 days, although there is a "clock stop" at day 120, to allow the company to respond to questions set forth in the Rapporteur and Co-Rapporteur's Assessment Report. When the company's complete response is received by the EMA, the clock restarts on day 121. If there are further aspects of the dossier requiring clarification, the EMA will then request an Oral Explanation on day 180, in which the sponsor must appear before the 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 update 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 ceases to be valid.

Japan

In Japan, applications for new products are made through the Pharmaceutical and Medical Devices Agency (PMDA). Once an NDA is submitted, a review team is formed consisting of specialized officials of the PMDA, including chemistry/manufacturing, non-clinical, clinical and biostatistics. While a team evaluation is carried out, a data reliability survey and Good Clinical Practice/Good Laboratory Practice/Good Manufacturing Practice inspection are carried out by the Office of Conformity Audit and Office of GMP/GQP Inspection 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

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

Price Controls

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

Direct efforts to control prices

United States. In the US, as a result of the Patient Protection and Affordable Care Act (ACA) and the recurring focus on deficit reduction, there is a significant risk of continued actions to control prices. Specifically, one proposal that has been repeatedly advanced would impose a government-mandated pricing formula on both patented and generic medications provided through the Medicare prescription drug benefit (Medicare Part D). In addition, the ACA mandated the creation of a new entity, the Independent Payment Advisory Board, which has been granted unprecedented authority to implement broad actions to reduce future costs of the Medicare program. This could include required prescription drug discounts or rebates, which could limit net prices for our products. There is a risk that government officials will continue to search for ways to reduce or control prices.

Europe. In Europe, our operations are subject to significant price and marketing regulations. Many governments are introducing healthcare reforms in a further attempt to curb increasing healthcare costs. In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general in the EU, particularly with regard to prescription drugs, has become very intense. Increasingly high barriers are being erected against the entry of new products, and payors are limiting access to innovative medicines based on cost-benefit analyses. In addition, prices for marketed products are referenced within Member States and across Member State borders, including new EU Member States.

Japan. In Japan, the government generally introduces price cuts every other year, and the government additionally mandates price decreases for specific products. In 2014, 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 became effective beginning April 2014. 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 2016.

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Rest of World. Many other countries around the world are also taking steps to rein in prescription drug prices. As an example, China, one of our most important emerging growth markets, has ordered price cuts on drugs five times since 2011, including 2013 price cuts of up to 20%.

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, including numerous European countries. 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.

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, would enable us to earn an adequate return on our investment in that product.

Intellectual Property

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

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United States

Patents

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

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

Data and Market Exclusivity

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

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

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

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

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

European Community

Patents

Patent applications in Europe may be filed in the European Patent Office (EPO) or in a particular country in Europe. The EPO system permits a single application to be granted for the whole of the EU, plus other non-EU countries, such as Switzerland and Turkey. A patent granted by the EPO or a European country office will expire no later than 21 years from the earliest patent application on which the patent is based. Pharmaceutical patents can also be granted a further period of exclusivity under the Supplementary Protection Certificate (SPC) system. SPCs are designed to compensate the owner of the patent for the time it took to receive marketing authorization by the European Health Authorities. An SPC may be granted to provide, in combination with the patent, up to 15 years of exclusivity from the date

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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, 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. This system has been in force since late 2005, therefore some medicines remain covered by the previous system in which EU member states provided either 6 or 10 years of data exclusivity.

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

Japan

In Japan, a patent can be issued for active pharmaceutical ingredients. Although methods of treatment, such as dosage and administration, are not patentable in Japan, pharmaceutical compositions for a specific dosage or administration method are patentable. Processes to make a pharmaceutical composition are also patentable. The patent term granted is generally 20 years from the filing date of the patent application on which the patent is based. It can be extended up to 5 years under the Japanese Patent Act to compensate for erosion against the patent term caused by the time needed to obtain marketing authorization from the MHLW. Typically, it takes approximately 7 to 8 years to obtain marketing authorization in Japan. A patent application on a pharmaceutical substance is usually filed shortly before or at the time when clinical testing begins. Regarding compound patents, it commonly takes approximately 4 to 5 years or more from the patent application filing date to the date that the patent is 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 10 to 15 years, if duly extended.

The following are additional details regarding the patent expiration dates and exclusivity for certain key products of our Pharmaceuticals Division:

Oncology

Gleevec/Glivec. We have patent protection on imatinib, the active ingredient in *Gleevec/Glivec*, until July 2015 in the US and until 2016 in the major European countries. The patent on the active ingredient expired in 2014 for the main indications in Japan. Additional patents were granted in

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more than 40 countries, including the US, Japan, France, Germany, UK, Italy and Spain, claiming innovative features of *Gleevec/Glivec*, including the crystal form (expiry 2018), tablet formulation (expiry 2023) and process (expiry 2023). Patent protection on the crystal form of imatinib was challenged in the US by generics manufacturers, but no challenge has been made to the compound patent in the US. In March 2014, litigation in the US against one such generic manufacturer was settled, which will allow that generic manufacturer to enter the US market on February 1, 2016. *Gleevec/Glivec* currently faces generic competition in a number of countries including Brazil, Canada, China, India, Russia, Turkey and for a minor indication in Japan. Litigation is also ongoing in Canada, Portugal, UK, South Korea and Mexico.

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

Afinitor and *Afinitor Disperz/Votubia* and *Zortress/Certican.* Everolimus, the active ingredient in these products is also licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents. Patent protection on everolimus (including the compound patent) has been challenged in the US.

Exjade. In the US and Canada, generic companies have challenged the compound patent for the active ingredient in *Exjade*. In the US, an automatic stay preventing the FDA from approving a generic version of *Exjade* expired in August 2014. Novartis settled one action against a generic company in the US in March 2014. Another action against a different generic manufacturer remains pending, with the automatic stay in this case expiring in November 2016. It is possible that the generic company may launch its generic version of *Exjade* after the automatic stay expires, or if we lose our patent litigation suit against it.

Femara. Generic versions of *Femara* are available now in all major markets with the exception of Japan.

Jakavi. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US.

Cardio-Metabolic

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 2022 in Europe and 2024 in Japan.

Immunology and Dermatology

Xolair. Potential biosimilar competitors have initiated biosimilarity trials in China. No biosimilarity trials have been initiated in highly-regulated markets such as the US, Europe and Japan.

Myfortic. In the US, four patent litigations have been settled and a generic version of *Myfortic* is currently available. Generic manufacturers are seeking approval for generic versions of *Myfortic* in some European countries.

Cosentyx. Patent protection for the active ingredient in *Cosentyx* is expected to expire in 2028 in the US, 2030 in Europe and 2029 in Japan.

Retina

Lucentis. Novartis licensed *Lucentis* from Genentech for development and commercialization outside the US.

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Respiratory

Ultibro. *Ultibro* is a product which combines indacaterol, the active ingredient in *Arcapta/Onbrez*, with glycopyrronium bromide, the active ingredient in *Seebri*. There is no compound patent protection on glycopyrronium, but there are patents and patent applications for the dry powder formulation technology that apply to both glycopyrronium and fixed-dose combination indacaterol/glycopyrronium products. In addition, there are patents and patent applications for the combination of indacaterol and glycopyrronium that are due to expire in 2025 worldwide (excluding extensions in some countries).

TOBI Podhaler. There is no patent protection for the active ingredient, tobramycin. Patents covering the commercial product will expire from 2018 to 2022 in the US and Europe. Additional patent applications are also pending with respect to the commercial product in the US and Europe, potentially providing protection until 2025. In addition, in Europe, *TOBI Podhaler* is entitled to orphan drug status until 2023 for the current approved indication. Regulatory data protection in the US expires in 2016.

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 and Japan (including a 5-year patent term extension). In Europe and Japan, we have regulatory exclusivity for the data generated for approval of *Gilenya* until 2021, which could possibly be extended by one year in Europe. A patent for the commercial formulation of *Gilenya* has been granted in most major markets (including Australia and Russia, where there is no compound patent). This patent will expire in 2024 in most countries, including Europe and Japan, and in 2026 in the US. Patent protection on fingolimod (including on the compound patent) has been challenged in the US.

Exelon. Patent protection on rivastigmine, the active ingredient in *Exelon*, has expired and *Exelon* capsules are subject to generic competition in major markets, including the US and all of Europe. We hold additional patents with respect to *Exelon* Patch. Four generic manufacturers have filed applications to market generic versions of *Exelon* Patch in the US, and have challenged the patents covering the *Exelon* Patch. We have filed infringement lawsuits against all of these manufacturers. Generic versions of *Exelon* Patch are on the market in several European countries. We are taking steps to enforce patents and trademarks protecting *Exelon* Patch against the manufacturers and distributors of patches which have challenged our intellectual property rights.

Stalevo. Patent litigation by Orion in the US against generic manufacturers settled and generic versions of *Stalevo* were launched in the US. Novartis was not a party to the US litigation. Generic manufacturers are seeking approval for generic versions of *Stalevo* in some European countries, and have launched in Germany.

Established Medicines

Cubicin. RDP in the EU for *Cubicin* expires in 2016. However, generic competitors may only submit for EU approval after 2016, and it may take additional time to obtain marketing authorization.

Diovan/Co-Diovan/Diovan HCT. In the EU, *Diovan* and *Co-Diovan* have faced generic competition since 2011, following expiration of the patent on valsartan. In the US, the valsartan patent expired in September 2012 and *Diovan HCT* has faced generic competition since then. Generic versions of *Diovan* monotherapy were launched in the US in May 2014. Patent protection expired in Japan in 2013 for *Diovan* and will expire in 2016 for *Co-Diovan* (including patent term extensions).

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Exforge/Exforge HCT. Patents covering *Exforge* (the combination of amlodipine besylate and valsartan) will expire in 2019 in the US and 2021 (including patent term extension) in Europe, and have been challenged in both the US and Europe. Since 2014, the product has faced generic competition in the US. We have regulatory data protection for *Exforge* in Europe until 2017, however, generic manufacturers may attempt to circumvent this regulatory exclusivity and seek to gain approval of a combination valsartan-amlodipine product in Europe before 2017. The patent covering *Exforge HCT* (the combination of amlodipine besylate, hydrochlorothiazide and valsartan) will expire in 2023 and has been challenged in the US and Europe.

Ritalin LA/Focalin XR. Several generic manufacturers have filed applications to market generic versions of *Ritalin LA* and *Focalin XR* in the US. Litigation against several generic manufacturers was initiated in the US but has since been settled. Generic versions of certain strengths of *Ritalin LA* and *Focalin XR* are now available in the US.

Compounds in Development

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

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 EMA:

LBH589. Patent protection for panobinostat, a pan HDAC (histone deacetylase) inhibitor is expected to expire in 2026 in the US, Europe and Japan.

LCZ696. Compound patent protection for the individual components, namely sacubitril and valsartan, has expired. Patents covering the combination of valsartan and sacubitril, as well as the LCZ696 salt complex, have been granted and expire in 2023 and 2026 (2027 in the US), respectively, without extensions. LCZ696 is entitled to post-approval regulatory exclusivity for five years in the US, 10 years in Europe and 8 years in Japan. We currently estimate that loss of exclusivity will occur in 2027 in the US, 2026 in the EU and 2030 in Japan.

LDE225. Patent protection for sonidegib, a smoothened inhibitor of the Hedgehog pathway, is expected to expire in 2029 in the US and 2027 in Europe, excluding extensions.

RLX030. Patent protection for the serelaxin molecule (human relaxin-2) has expired and the patents covering the formulation and process will expire prior to the product's projected launch date. A patent covering the method of using serelaxin to treat acute heart failure has been granted in the US and expires in 2029. This use patent is now under examination worldwide in markets that

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permit use patents. Serelaxin is entitled to post-approval regulatory exclusivity for 12 years in the US, 11 years in Europe and eight years in Japan.

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

ALCON

Our Alcon Division is a leader in the research, development, manufacturing and marketing of eye care products worldwide. As of December 31, 2014, the Alcon Division employed 23,900 full-time equivalent associates worldwide in 75 countries. In 2014, the Alcon Division had consolidated net sales of $10.8 billion representing 19% of total Group net sales.

Alcon is a global leader in eye care and 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 franchises: Surgical, Ophthalmic Pharmaceuticals and Vision Care. Alcon products are available in more than 180 markets. Each franchise operates with specialized sales forces and marketing support.

Alcon's dedication to research and development is important to our growth plans. As part of our efforts, the Alcon Division works together with the Novartis Institutes for BioMedical Research (NIBR), our global pharmaceutical research organization. This collaboration allows our Alcon Division to leverage the resources of NIBR in an effort to discover and expand ophthalmic pharmaceutical research targets and to develop chemical and biologic compounds for the potential treatment of diseases of the eye, with a particular focus on diseases such as glaucoma and macular degeneration.

In July 2014, Alcon entered into an agreement with Google [x] to license its "smart lens" technology with the potential to address ocular conditions. In October 2014, Alcon acquired WaveTec Vision. The acquisition provided Alcon with the *ORA* System, the first commercialized intra-operative guidance system for cataract surgeons implanting intraocular lenses (IOLs). Alcon plans to integrate the *ORA* System into its existing *Cataract Refractive Suite* by Alcon.

In March 2012, Alcon gained exclusive rights from ThromboGenics to commercialize *Jetrea* (ocriplasmin) intravitreal injection outside the US. *Jetrea* is the first pharmacological treatment for vitreomacular traction, including macular hole, in Europe. *Jetrea* was approved for sale in the EU in 2013.

In July 2012, Alcon acquired Endure Medical Systems. The acquisition enabled Alcon to enter into the ophthalmic microscopy field through the addition of the *LuxOR* microscope, which has applications for both cataract, as well as vitreoretinal surgeries. *LuxOR* products were introduced globally in 2013.

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

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Alcon Division Products

Surgical

Our Alcon Division's Surgical franchise is the market leader in global ophthalmic surgical product revenues, 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 *Cataract Refractive Suite* by Alcon, a suite of equipment to help plan and perform some of the most challenging steps of cataract surgery with automation and precision. It is comprised of the *Centurion* vision system phacoemulsification technology platform; the *LenSx* laser, a femtosecond laser for increased precision and reproducibility for the corneal incision, capsulorhexis and lens fragmentation steps of the procedure; the *Verion* image guided system, an ocular surgical planning, imaging and guidance technology; the *ORA System*, an intra-operative guidance system for IOL implantation during cataract surgery; and the *LuxOR LX3* surgical microscope for greater visualization during surgery. The portfolio also includes the *Infiniti* vision system to perform cataract surgeries, which is the phacoemulsification platform introduced prior to the *Centurion* vision system, the *Constellation* vision system for retinal operations, and the *WaveLight* refractive suite for refractive procedures and Lasik treatments. Alcon also offers the *AcrySof* family of intraocular lenses (IOLs) to treat cataracts, including the *AcrySof IQ*, *AcrySof IQ ReSTOR, AcrySof IQ Toric* and *AcrySof IQ ReSTOR Toric* IOLs. 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 franchise develops and markets a broad range of pharmaceuticals to treat chronic and acute conditions of the eye including glaucoma, elevated intraocular pressure (associated with glaucoma), eye infection and inflammation, eye allergies, dry eye and retinal diseases. Ophthalmic Pharmaceuticals also oversees the line of professionally driven over-the-counter brands that include artificial tears and ocular vitamins. Product highlights within the Ophthalmic Pharmaceuticals portfolio include *Ilevro* ophthalmic suspension for the treatment of pain and inflammation associated with cataract surgery; *Simbrinza* suspension to lower intraocular pressure as a fixed-dose combination; *Travatan Z, Izba* and *DuoTrav*, each ophthalmic solutions for the treatment of elevated intraocular pressure associated with open-angle glaucoma or ocular hypertension; *Vigamox* ophthalmic solution for bacterial conjunctivitis; *Pataday* ophthalmic solution for ocular itching associated with allergic conjunctivitis; *Nevanac* ophthalmic suspension for eye pain and inflammation following cataract surgery, and to reduce the risk of macular edema associated with cataract surgery in diabetic patients; the *Systane* family of over-the-counter products for dry eye relief; and *Jetrea* intravitreal injection for treating vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns.

Vision Care

Our Alcon Division's Vision Care franchise develops and markets contact lenses and lens care products. Alcon's broad portfolio of silicone hydrogel, daily disposables and color contact lenses includes our *Air Optix*, *Dailies* and *Freshlook* brands. Our *Dailies* product line includes *Dailies Total1* lenses, a first-of-its-kind water gradient contact lens. Our *Air Optix* product line now includes the new *Air Optix Colors* silicone hydrogel contact lenses. Our contact lens care solutions business includes the *Opti-Free* line of multi-purpose disinfecting solutions and drops, as well as the *Clear Care* and *AOSept Plus* hydrogen peroxide lens care solutions.

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New Products

Alcon launched a number of significant products in 2014, and also received a number of key approvals, including:

27+ vitrectomy packs for use during micro-incision vitrectomy surgery were launched globally.

AcrySof ReSTOR 2.5D intraocular lens for distance vision correction during cataract surgery approved in Japan.

AcrySof IQ ReSTOR Toric 3.0D intraocular lens: multifocal lens with astigmatism correction during cataract surgery approved in Japan.

AOSept Plus/Clear Care Plus with *HydraGlyde* lens care solution was approved and launched in the EU.

Air Optix Colors contact lenses: silicone hydrogel, color cosmetic monthly contact lenses received approval and was launched in the US and EU.

Centurion vision system: phacoemulsification surgical platform for cataract surgery was approved in Japan.

Dailies AquaComfort Plus toric lenses: daily disposable contact lenses for improving refractive errors, such as astigmatism, was launched in the US and select EU countries.

Dailies AquaComfort Plus multifocal lenses: daily disposable contact lenses for improving refractive errors, such as presbyopia, was launched in the US and select EU countries.

Dailies Total1 daily disposable, water gradient contact lenses launched in Australia, Hong Kong and Japan.

DuoTrav (travoprost/timolol) solution was approved and launched in China for the treatment of elevated intraocular pressure associated with open-angle glaucoma or ocular hypertension.

Finesse flex loop: new *Grieshaber* instrument was launched globally for use during vitreoretinal surgical procedures.

Izba (travoprost 0.003%) solution received US and EU approvals for the treatment of elevated intraocular pressure associated with open-angle glaucoma or ocular hypertension, and was launched in Denmark, Sweden, Romania, Finland and Norway.

LenSx Laser was approved in Japan for use during cataract surgery.

LuxOR LX3 microscope system was approved in the US and EU for use during surgical procedures.

Opti-Free Pro rewetting drops and lubricant eye drops received approval and was launched in select EU markets.

Simbrinza (brinzolamide, 1.0%/brimonidine tartrate 0.2%) suspension received EU approval for the treatment of elevated intraocular pressure associated with glaucoma, was launched in the UK, Denmark and the Netherlands.

Travatan (40µg/mL travoprost) eye drops solution, receives EU approval for the decrease in elevated intraocular pressure in pediatric patients, aged two months to less than 18 years, with ocular hypertension or pediatric glaucoma

UltraVit 7500 vitrectomy probes was launched globally for the use during vitreoretinal surgical procedures.

Verion surgical planning system was approved in Japan, and was launched in the US and EU for use during cataract surgery.

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Key Marketed Products

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

Surgical

Cataract	*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 and distance vision with presbyopia and/or astigmatism
	Cataract Refractive Suite by Alcon designed to streamline the cataract surgical procedure through surgical planning and execution
	Centurion vision system intelligent phacoemulsification technology platform with cataract removal capabilities
	Infiniti vision system with the *OZil* torsional hand piece for cataract procedures
	LenSx laser used for specific steps in the cataract surgical procedure
	LuxOR microscope used for ophthalmic surgical procedures
	ORA System intra-operative guidance system for intraocular lens implant during cataract surgery
	Verion imaged-guided system for use during cataract surgery
Vitreoretinal	*Constellation* vision system for vitreoretinal operations
	Ultravit vitrectomy probes
	23+, 25+ and 27+ vitrectomy packs
	Purepoint laser system and probes
	Finesse flex loop
	Grieshaber surgical instruments
	Edgeplus blade trocar cannula system
	Ispan gas, *Perfluron, Silkon* oil: Retina stabilizing adjuncts
Refractive	*Allegretto Wave Eye-Q* excimer laser for LASIK vision correction
	WaveLight FS200 laser for specific steps in LASIK surgical procedures
	WaveLight EX500 laser for LASIK vision correction
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

Glaucoma	*Simbrinza* suspension to lower intraocular pressure without a beta blocker
	Travatan and *Travatan Z* ophthalmic solutions to lower intraocular pressure
	Izba solution to lower intraocular pressure
	Azopt ophthalmic suspension to lower intraocular pressure
	DuoTrav ophthalmic solution to lower intraocular pressure (outside US markets)
	Azarga/Azorga ophthalmic suspension to lower intraocular pressure (outside US markets)
	Nyogel eye gel for reduction of intraocular pressure

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Anti-Infectives	*Vigamox* and *Moxeza* ophthalmic solution for treatment of bacterial conjunctivitis
Anti-Inflammation	*Ilevro* suspension to treat pain and inflammation following cataract surgery
	Nevanac ophthalmic suspension to treat pain and inflammation following cataract surgery, and to reduce the risk of macular edema associated with cataract surgery in diabetic patients
	Durezol emulsion to treat pain and inflammation associated with eye surgery, and to treat endogenous anterior uveitis
	TobraDex and *TobraDex ST* ophthalmic suspensions, combination anti-infective/anti- inflammatory products
	Voltaren ophthalmic solution to treat post-operative inflammation after cataract surgery, and for temporary relief of pain and photophobia after refractive surgery
Dry Eye	The *Systane* family of over-the-counter dry eye products:
	Systane lubricant eye drops
	Systane Balance lubricant eye drops
	Systane Ultra lubricant eye drops
	Systane gel drops
	Systane lid wipes
	Lubricants for eye dryness, discomfort or ocular fatigue:
	GenTeal lubricant eye drops
	Tears Naturale lubricant eye drops
	Oculotect eye drops (outside US markets)
Allergy	*Patanol* and *Pataday* ophthalmic solutions for ocular itching associated with allergic conjunctivitis
	Patanase nasal spray for seasonal nasal allergy symptoms
	Zaditor antihistamine eye drops for temporary relief of itchy eyes associated with eye allergies (over-the-counter in the US)
	Zaditen Ophtha an H1-antagonist to fight allergic conjunctivitis
	Livostin an H1-antagonist to fight allergic conjunctivitis (Canada only)
Ear Infections	*Ciprodex*[*] otic suspension to treat middle and outer ear infections
Ocular Nutrition	*ICaps* eye vitamin dietary supplements provide essential dietary ingredients to support eye health
	Vitalux nutrient supplements help patients with age-related macular degeneration maintain their vision (outside US markets)
Retinal	*Jetrea* (ocriplasmin) intravitreal injection for the treatment of vitreomacular traction, including macular hole
	Triesence suspension for visualization during vitrectomy

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* *Ciprodex* is a registered trademark of Bayer Intellectual Property GmbH.

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Vision Care

Contact Lenses	*Air Optix* family of silicone hydrogel contact lenses (including *Air Optix Colors* lenses) *Dailies* family of daily disposable contact lenses (including *Dailies Total1* lenses) *FreshLook* family of color contact lenses
Contact Lens Care	*Opti-Free PureMoist* MPDS *Opti-Free RepleniSH* MPDS *Opti-Free Express* MPDS *Clear Care* cleaning and disinfecting solution (*AOSept Plus* outside of North America)

Selected Development Projects

Surgical

Project/Product	Mechanism of action	Potential indication	Planned submission date/Current Phase
AcrySof IQ ReSTOR 2.5D IOL	Multifocal aspheric intraocular lens	Cataractous lens replacement with or without presbyopia	Submitted US
AcrySof IQ ReSTOR Toric 2.5D IOL	Multifocal, aspheric and cylinder correcting intraocular lens	Cataractous lens replacement with or without presbyopia, and with astigmatism	2015 US/Advanced development Submitted Japan
AcrySof IQ ReSTOR Toric 3.0D IOL	Multifocal, aspheric and cylinder correcting intraocular lens	Cataractous lens replacement with or without presbyopia, and with astigmatism	Submitted US
AcrySof IQ ReSTOR Toric 3.0D diopter range expansion IOL	Multifocal, aspheric and cylinder correcting intraocular lens	Cataractous lens replacement with or without presbyopia, and with astigmatism	2016 US and Japan/Advanced development

Ophthalmic Pharmaceuticals

Project/Product*	Mechanism of action	Potential indication	Route of Administration	Planned submission date/Current Phase
EXE844b (finafloxacin)	Anti-infective	Otitis media-tympanostomy tube surgery	Topical	2016 US/III
EXZ829 (olopatadine hydrochloride)	Antihistamine and mast cell stabilization	Allergic conjunctivitis	Topical	Submitted US
RTH258	Anti-VEGF single-chain antibody fragment	Wet age-related macular degeneration	Intravitreal injection	≥ 2017/III

*

EXE044 was approved by the FDA in 2014 as *Xtoro* (finafloxacin otic suspension, 0.3%). However, we do not plan to commercialize this product.

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Vision Care

Project/Product*	Mechanism of action	Potential indication	Planned submission date/Current Phase
AOSept Plus/Clear Care Plus with *HydraGlyde*	Disinfection and cleaning	Contact lens care	Submitted US 2016 Japan/ Advanced development

*

Development of CLM041 was discontinued in 2014. LCE293 is now disclosed as *AOSept Plus/Clear Care Plus* with *HydraGlyde*.

Principal Markets

The principal markets for our Alcon Division include the US, Canada and Latin America, Japan and Europe. The following table sets forth the aggregate 2014 net sales of the Alcon Division by region:

Alcon Division	2014 Net Sales to third parties	
	$ millions	%
Europe	2,872	27
United States	4,349	40
Asia, Africa, Australasia	2,449	23
Canada and Latin America	1,157	10
Total	**10,827**	**100**

	$ millions	%
Established Markets*	8,049	74
Emerging Growth Markets*	2,778	26
Total	**10,827**	**100**

*

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

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

Research and Development

In 2014, our Alcon Division expensed $0.9 billion (on a core basis $0.9 billion) in research and development, which amounted to 9% of the Division's net sales. The Alcon Division expensed $1.0 billion (on a core basis $0.9 billion) and $1.0 billion (on a core basis $1.0 billion) in research and development in 2013 and 2012, respectively.

Our Alcon Division associates in research and development work 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 invests approximately $1 billion annually to drive research and new product development in eye care. Alcon's pipeline strategy is built around a proof-of-concept qualification process, which quickly identifies opportunities that have the best chance for technical success and advances those projects, while terminating others with a low probability of success.

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In addition, 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 Ophthalmic Pharmaceuticals franchise, NIBR engages in research activities in an effort to discover and expand ophthalmic research targets, and to develop chemical and biologic compounds for the potential treatment of diseases of the eye, with a particular focus on diseases such as glaucoma and macular degeneration. The costs for these activities are allocated to Alcon.

Research and development activities for Alcon's Surgical franchise are focused on expanding intraocular lens capabilities to improve refractive outcomes and on developing instruments for cataract, vitreoretinal and corneal refractive surgeries. The focus for the Vision Care franchise is on the research and development of new lens materials, coatings and designs to improve patient comfort, and on lens care solutions that provide the safety, disinfecting and cleaning power needed to help maintain ocular health. As announced in 2014, Alcon is also collaborating with Google [x], and has licensed its smart lens technology for ocular medical uses, including the potential to monitor glucose levels in diabetic patients and provide an accommodative contact lens/intraocular lens for patients living with presbyopia. The Ophthalmic Pharmaceuticals franchise is focused on the development of products for the treatment of retinal diseases, glaucoma (intraocular pressure lowering) and ocular allergy.

Production

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

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

The manufacture of our products is complex and heavily regulated, which means that supply is never guaranteed. Like our competitors, our Alcon Division has faced manufacturing issues and has received Warning Letters relating to such manufacturing issues. In particular, in December 2012, Alcon received an FDA Warning Letter following an inspection at the *LenSx* laser manufacturing site in Aliso Viejo, California. Alcon responded in writing to the FDA, and in February 2013, FDA responded to Alcon acknowledging that the corrective actions described in Alcon's written response appear to address the items identified in the Warning Letter. The Warning Letter was lifted in May 2014 after all corrective actions were completed. The items noted in the Warning Letter did not affect the safety or effectiveness of the *LenSx* laser, or impact Alcon's ability to sell the product. If we or our third-party suppliers fail to comply fully with regulations then there could be a product recall or other shutdown or disruption of our production activities. We have implemented a global manufacturing strategy to maximize business continuity in case of such events or other unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

Marketing and Sales

Our Alcon Division conducts sales and marketing activities around the world organized under five operating regions (US, Europe/Middle East/Africa, Latin America/Caribbean/Canada, Asia and Japan). The Alcon Division's global commercial capability is organized around sales and marketing organizations dedicated to the Surgical, Ophthalmic Pharmaceuticals and Vision Care franchises.

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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 Ophthalmic Pharmaceuticals and Vision Care franchises, direct-to-consumer marketing campaigns are executed to promote selected products.

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

As a result of changes in healthcare economics, managed care organizations are now one of the largest groups 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 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. Our Alcon Division typically competes with different companies across its three respective franchises Ophthalmic Pharmaceuticals, Surgical and Vision Care. 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. Our principal competitors also sometimes form strategic alliances and enter into co-marketing agreements in an effort to better compete with us.

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 that 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.

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

Intellectual Property

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

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

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

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

SANDOZ

Our Sandoz Division is a leader in developing, manufacturing and marketing generic pharmaceutical products, follow-on biopharmaceutical products known as biosimilars, and drug substances that are not protected by valid and enforceable third-party patents. As of December 31, 2014, affiliates of the Sandoz Division employed 26,423 full-time equivalent associates worldwide, and sold products in more than 160 countries. In 2014, the Sandoz Division achieved consolidated net sales of $9.6 billion, representing 16% of the Group's total net sales.

Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals & Oncology Injectables. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. Retail Generics includes the specialty areas of Dermatology, Respiratory and Ophthalmics, as well as cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies.

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In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products (known as biosimilars or follow-on biologics) and provides biotechnology manufacturing services to other companies, and in Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

Sandoz has three strategic priorities: to differentiate Sandoz based on its extensive global reach and advanced technical expertise in the development, manufacturing and marketing of differentiated generics, including medicines that are difficult to develop and manufacture, and biosimilars, to be first-to-market as originators' substance patents expire or become unenforceable, and to be cost competitive by leveraging economies of scale in production and development. Sandoz differentiated products are comprised of biosimilars and generic injectables, ophthalmics, dermatologics, and respiratory, as well as difficult-to-make oral solids (such as tacrolimus).

According to IMS Health, Sandoz is the second-largest company in worldwide generic sales and is the global leader in biosimilars, with three marketed medicines accounting for over half of all biosimilars sales in the combined regions of North America, Europe, Japan and Australia. In addition, we have a pipeline of several biosimilar molecules under development and in registration, including biosimilar rituximab (sold by Roche under the brand names Rituxan®/MabThera®) and biosimilar etanercept (sold by Amgen and Pfizer under the brand name Enbrel®).

In 2014, Sandoz launched 28 new products in the US including authorized generic versions of our Pharmaceuticals Division products *Diovan* (valsartan), *Focalin XR* (dexmethylphenidate ER) and *TOBI* (tobramycin inhalation solution, USP); as well as cyclophosphamide injection, USP; calcipotriene and betamethasone dipropionate ointment (Taclonex®, Leo Pharma); adapalene gel (Differin®, Galderma Laboratories); lansoprazole capsules, amoxicillin capsules, USP, and clarithromycin tablets, USP (PREVPAC®, Takeda Pharmaceuticals); the injectable decitabine (Dacogen®, Eisai), and Kerydin (tavaborole) topical solution, 5% after obtaining exclusive rights from Anacor Pharmaceuticals to commercialize it in the US through Sandoz's branded dermatology business, PharmaDerm. Furthermore, Sandoz reached an agreement with Upsher-Smith to obtain exclusive US distribution rights for its branded potassium chloride product line, Klor-Con®.

Key product launches in various European countries include *AirFluSal Forspiro*, a respiratory product that offers the proven combination of salmeterol (a long-acting inhaled $beta_2$-agonist) and fluticasone propionate (an inhaled corticosteroid) for asthma and chronic obstructive pulmonary disease patients in an innovative inhalation device, *Vitaros* (alprostadil), an innovative topical therapy for erectile dysfunction, escitalopram (Cipralex®, Lundbeck), and mometasone (the first generic version of Nasonex®, Merck Sharp & Dohme), which was launched in additional European countries in 2014 following launches in several European countries in 2013.

In Biopharmaceuticals, Sandoz continued to strengthen its global leadership in biosimilars, and to drive its contract manufacturing base business. Sandoz biosimilars are sold in over 60 countries. In addition, all three Sandoz biosimilar products continue to occupy the number one biosimilar position in terms of market share in their respective markets. According to IMS data, Sandoz' recombinant growth hormone *Omnitrope* was the fastest growing hGH treatment globally by volume. *Omnitrope*, which is now marketed in over 40 countries, was also among Sandoz's top three products in terms of sales. In 2014, Sandoz continued to roll out *SurePal*, an innovative device that provides patients with a simple and secure way to inject *Omnitrope*.

Anemia medicine *Binocrit* continued to demonstrate strong growth in several European countries as a short-acting erythropoietin stimulating agent (ESA). It is the leading biosimilar in its category by volume across Europe (short-acting only). Sandoz G-CSF biosimilar, *Zarzio*, continued to strengthen its leading

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position as the number one filgrastim product in Europe by volume, ahead of Amgen's Neupogen® and Chugai's Granocyte®.

Sandoz continued to make significant progress on its biosimilar pipeline in 2014 and now has six molecules in Phase III clinical trials or registration. In 2014, Sandoz completed Phase III trials for biosimilar pegfilgrastim (Neulasta®, Amgen) for global registration, and completed patient enrollment in its Phase III clinical trial for biosimilar entanercept (Enbrel®, Amgen).

In addition, in 2014, Sandoz made significant progress with respect to biosimilar filgrastim (Neupogen®, Amgen). Sandoz received marketing authorization for the product in Japan. In the US, Sandoz completed Phase III trials, and the FDA accepted Sandoz's BLA for filgrastim, which was filed under the biosimilar pathway of the BLA. Sandoz is the first company to announce it has filed for approval of a biologic under the biosimilars pathway created in the Biologics Price Competition and Innovation Act of 2009. Subsequently, in January 2015, the FDA Oncologic Drugs Advisory Committee recommended approval of Sandoz's filgrastim for use in all indications in the reference product's label.

In December 2013, Sandoz received Danish marketing authorization for *AirFluSal Forspiro*. This was Sandoz's first European approval for this product and followed the completion of EU decentralized procedures (DCP) for eight EU countries. Since then, *AirFluSal Forspiro* has received marketing authorizations in a total of 15 European countries, as well as South Korea and Mexico, and been launched in four European countries and South Korea. These approvals and launches of *AirFluSal Forspiro* are a key element of Sandoz's strategy to introduce differentiated generic medicines and innovative products.

In 2014, Sandoz continued to accelerate its efforts across Sub-Saharan Africa, supported by a strong product portfolio that comprises anti-infectives, tuberculosis treatments, maternal and child health products, and medicines to address non-communicable diseases. In 2014, Sandoz established branch offices in Cameroon, Kenya and Zambia.

New Products

Sandoz launched a number of important products in various countries in 2014, including:

Valsartan (*Diovan)*

Cyclophosphamide injection, USP

AirFluSal Forspiro

Kerydin (tavaborole) topical solution, 5%

Vitaros (alprostadil)

Dexmethylphenidate ER (*Focalin XR)*

Tobramycin inhalation solution, USP (*TOBI*)

Calcipotriene and betamethasone dipropionate ointment, (Taclonex®, Leo Pharma)

Adapalene gel (Differin®, Galderma Laboratories)

Lansoprazole capsules, amoxicillin capsules, USP, and clarithromycin tablets, USP (PREVPAC®, Takeda Pharmaceuticals)

Decitabine (Dacogen®, Eisai)

Escitalopram (Cipralex®, Lundbeck)

Mometasone (Nasonex®, Merck Sharp & Dohme)

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Key Marketed Products

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

Retail Generics

Product	Originator Drug	Description
Valsartan	*Diovan*	High blood pressure and heart failure
Amoxicillin/clavulanic acid	Augmentin®	Anti-infective
Enoxaparin sodium injection	Lovenox®	Anti-coagulant
Acetylcysteine	Fluimicil®	Respiratory system
Fentanyl	Duragesic®	Analgesic
Omeprazole	Prilosec®	Ulcer and heartburn treatment
Linex (lactobacillus)	n/a	Dietary supplement
Tacrolimus	Prograf®	Transplantation
Sumatriptan	Imitrex®, Imigran®	Migraine headaches
Atorvastatin	Lipitor®	Blood cholesterol reduction
Diclofenac	*Voltaren*	Analgesic

Anti-Infectives

Active Ingredients	Description
Oral and sterile penicillins	Anti-infectives
Oral and sterile cephalosporins	Anti-infectives
Clavulanic acid and mixtures with clavulanic acid	ß-lactam inhibitors
Classical and semisynthetic erythromycins	Anti-infectives

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

Biopharmaceuticals

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

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Oncology Injectables

Product	Originator Drug	Description
Leuprorelin	Lupron®, Eligard®	Prostate cancer
Docetaxel	Taxotere®	Breast, ovarian and non-small cell lung cancer
Methotrexate	Folex®, Rheumatrex®	Arthritis; breast, lung, cervix and ovarian cancer, and others
Azacitidine	Vidaza®	Bone marrow cancer, leukemia
Paclitaxel	Taxol®	Breast, lung and ovarian cancer, Kaposi sarcoma
Gemcitabine	Gemzar®	Bladder, pancreas, lung, ovarian, and breast cancer
Etoposide	Etopophos®, Vepesid®	Lung, ovarian, and testicular cancer
Oxaliplatin	Eloxatin®	Colorectal and colon cancer
Irinotecan	Camptosar®	Colon and Rectal cancer
Doxorubicin	Doxil®, Adriamycin®	Leukemia, breast, bone, lung and brain cancer, many types of carcinoma and soft tissue sarcomas

Biosimilars in Phase III Development and Registration

The following table describes Sandoz's biosimilar projects that are in Phase III clinical trials and registration:

Project/product	Common name	Mechanism of action	Potential indication/ indications	Therapeutic areas	Route of administration	Current phase
EP2006	filgrastim	Granulocyte colony-stimulating factor	Chemotherapy-induced neutropenia, mobilization of peripheral blood progenitor cells and others (same as originator)	Oncology	Subcutaneous and intravenous	US Registration
GP2013	rituximab	Anti-CD20 antibody	Non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis (also known as Wegener's granulomatosis), and microscopic polyangiitis and others (same as originator)	Oncology and Immunology	Intravenous	II and III
GP2015	etanercept	TNF-α inhibitor	Arthritidies (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis), plaque psoriasis and others (same as originator)	Immunology	Subcutaneous	III
GP2017	adalimumab	TNF-α inhibitor	Arthritidies (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis), plaque psoriasis and others (same as originator)	Immunology	Subcutaneous	III
HX575*	epoetin alfa	Erythropoiesis-stimulating agent	Chronic kidney disease, chemotherapy-induced anemia and others (same as originator)	Oncology and Nephrology	Subcutaneous and intravenous	III
HX575 s.c.**	epoetin alfa	Erythropoiesis-stimulating agent	Chronic kidney disease	Oncology and Nephrology	Subcutaneous	III
LA-EP2006	pegfilgrastim	Pegylated granulocyte colony-stimulating factor	Chemotherapy-induced neutropenia and others (same as originator)	Oncology	Subcutaneous	III

*
Planned submission for US.

**

Planned submission for EU (extension nephrology). Approved as *Binocrit* since 2007.

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Principal Markets

The two largest generics markets in the world the US and Europe are the principal markets for Sandoz, although Sandoz sells products in more than 160 countries. The following table sets forth the aggregate 2014 net sales of Sandoz by region:

Sandoz	2014 Net Sales to third parties	
	$ millions	%
Europe	4,573	48
United States	3,215	34
Asia, Africa, Australasia	1,168	12
Canada and Latin America	606	6
Total	**9,562**	**100**

	$ millions	%
Established Markets*	7,035	74
Emerging Growth Markets*	2,527	26
Total	**9,562**	**100**

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

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

Production

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

We manufacture and package our Sandoz products at 45 manufacturing sites across 19 countries, supplying more than 160 countries globally. Among these, our most significant production facilities are located in Barleben and Rudolstadt, Germany; Kundl, Schaftenau and Unterach, Austria; Ljubljana, Slovenia; Stryków, Poland. We are implementing a global manufacturing strategy that focuses on building a high-quality manufacturing network that optimizes cost, service, technology and geography.

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

Where possible, we maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers, and competitive material sourcing can be assured. However, our ability to

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do so may at times be limited by regulatory or other requirements. We monitor market developments that could have an adverse effect on the supply of essential active pharmaceutical ingredients. All active pharmaceutical ingredients we purchase must comply with high quality standards.

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

In July 2014, the FDA confirmed that it had decided to close out the Warning Letter issued in November 2011 against three of Sandoz's North American facilities in Broomfield, Colorado; Wilson, North Carolina; and Boucherville, Canada. The Warning Letter, which followed inspections at all three sites in the course of 2011, had raised concerns regarding these facilities' compliance with FDA cGMP regulations. The FDA observations in the Warning Letter related primarily to general documentation, validation and investigation practices. Novartis took steps in collaboration with the FDA to correct the observations in the Warning Letter with respect to all three sites.

In May 2013, we received a Warning Letter from the FDA concerning the oncology injectables manufacturing facility in Unterach, Austria. The letter contained two observations which followed an FDA inspection at the site in October 2012, and are related to historical visual inspection practices for products manufactured at the site. We are collaborating with the FDA to correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet the highest quality standards. A follow-up inspection by the FDA in 2014 resulted in no observations.

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

Marketing and Sales

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

In response to rising healthcare costs, many governments and private medical care providers, such as health maintenance organizations, have instituted reimbursement schemes that favor the substitution of bioequivalent generic products for patented pharmaceutical products. In the US, statutes have been enacted by virtually all states that permit or require pharmacists to substitute a less expensive generic product for the brand-name version of a drug that has been prescribed to a patient. Generic use is growing in Europe, but penetration rates in many EU countries (as a percentage of volume) remain well below those in the US. Legislative or regulatory changes can have a significant impact on our business in a country. In Germany, for example, the generic market is in transition and healthcare reforms have increasingly shifted decision making from physicians to insurance funds.

Our Anti-Infectives franchise supplies generic antibiotics to a broad range of customers, as well as active pharmaceutical ingredients and intermediates to the pharmaceutical industry worldwide.

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

Competition

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

In addition, research-based pharmaceutical companies have responded to increased competition from generic products by licensing their patented products to generic companies (so-called "authorized generics"). By doing so, research-based pharmaceutical companies participate directly in the generic conversion process. Consequently, generic companies that were not in a position to compete on a specific product may enter the generic market using the innovator's product. In the US, the authorized generic is not subject to the US Hatch-Waxman Act rules regarding exclusivity (see " Regulation"). The company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder. Authorized generics serve as a business opportunity for Sandoz when the product of a research-based pharmaceutical company loses patent protection and Sandoz secures a license from the research-based pharmaceutical company to launch the authorized generic of that product. However, because they are not subject to the Hatch-Waxman Act rules on exclusivity, authorized generics also reduce the value of the exclusivity for the company that invested in creating the first generic medicine to compete with the originator product. Furthermore, certain research-based companies continually seek new ways to protect their market franchise and to decrease the impact of generic competition. For example, some research-based pharmaceutical companies have reacted to generic competition by decreasing the prices of their patented product, or engaging in other tactics to preserve the sales of their branded products, thus potentially limiting the profit that the generic companies can earn on the competing generic product.

Development and Registration

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

While generic pharmaceuticals are follow-on versions of chemically synthesized molecules, so-called "biosimilar" products contain a version of the active substance of an already approved original biological medicine. Due to the inherent variability of biologic products and their higher complexity, the development and the regulatory pathway of biosimilars differ significantly from that of generics.

Development of a biosimilar product is much more technically challenging than the development of a generic pharmaceutical. Unlike generic pharmaceuticals, development of biosimilars requires clinical

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studies in patients. Biosimilars are engineered to match the reference product in quality, safety and efficacy. This is achieved by systematically defining the target of the reference product and then comparing the biosimilar to the reference product at various development stages to confirm biosimilarity and to establish that there are no clinically meaningful differences between the proposed biosimilar and the reference biologic. Because the purpose of a biosimilar clinical development program is to confirm biosimilarity and not establish efficacy and safety de novo, the clinical studies required are less than those required for an originator biologic, and no pre-clinical studies are required. Therefore, the cost of development for a biosimilar is usually less than that of an originator biologic.

The regulatory pathways for approval of biosimilar products are being developed and established in many countries of the world. A regulatory framework for the approval of biosimilars has been established in the EU, Japan, Canada and US, while the WHO issued guidance. Sandoz has successfully registered and launched the first biosimilar (or biosimilar type) product in Europe, the US, Canada, Japan, Taiwan, Australia and many countries in Latin American and Asia. Sandoz has three approved biosimilar products in more than 60 countries of the world, and is the first company to file a Biologics License Application (BLA) for marketing approval of a biosimilar in the US.

Currently, the affiliates of the Sandoz Division employ more than 2,700 Development and Registration staff who explore alternative routes for the manufacture of known compounds and develop innovative dosage forms of well-established medicines. These associates are based worldwide, including facilities in Holzkirchen and Rudolstadt, Germany; Kundl, Schaftenau and Unterach, Austria; Ljubljana and Mengeš, Slovenia; Boucherville, Canada; and East Hanover, New Jersey. In 2014, Sandoz expensed $0.8 billion (on a core basis $0.8 billion) in product development, which amounted to 8% of the division's net sales. Sandoz expensed $0.8 billion (on a core basis $0.8 billion) and $0.7 billion (on a core basis $0.7 billion, as a result, in part, of a decrease of a contingent consideration liability related to a business combination) in 2013 and 2012, respectively.

Regulation

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

In the US, the decision whether a generic pharmaceutical is bioequivalent to the original patented product is made by the FDA based on an Abbreviated New Drug Application (ANDA) filed by the generic product's manufacturer. The process typically takes nearly two years from the filing of the ANDA until FDA approval. However, delays can occur if issues arise regarding the interpretation of bioequivalence study data, labeling requirements for the generic product, or qualifying the supply of active ingredients. In addition, the Hatch-Waxman Act requires a generic manufacturer to certify in certain situations that the generic product does not infringe on any current applicable patents on the product held by the innovator, or to certify that such patents are invalid or the product is non-infringing. This certification often results in a patent infringement lawsuit being brought by the patent holder against the generic company. In the event of such a lawsuit, the Hatch-Waxman Act imposes an automatic 30 month delay in the approval of the generic product in order to allow the parties to resolve the intellectual property issues. For generic applicants who are the first to file their ANDA containing a certification claiming non-infringement or patent invalidity, the Hatch-Waxman Act provides those applicants with 180 days of marketing exclusivity to recoup the expense of challenging the innovator patents. However, generic applicants must launch their products within certain time frames or risk losing the marketing exclusivity that they had gained by being a first to file applicant.

In the EU, decisions on the granting of a marketing authorization are made either by the European Commission based on a positive recommendation by the EMA under the Centralized Procedure, or by a single Member State under the national or decentralized procedure. See " Pharmaceuticals

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Regulation European Union." Companies may submit Abridged Applications for approval of a generic medicinal product based upon its "essential similarity" to a medicinal product authorized and marketed in the EU following the expiration of the product's data exclusivity period. In such cases, the generic company is able to submit its Abridged Application based on the data submitted by the medicine's innovator, without the need to conduct extensive Phase III clinical trials of its own. For all products that received a marketing authorization in the EU after late 2005, the Abridged Application can be submitted throughout the EU. However, the data submitted by the innovator in support of its application for a marketing authorization for the reference product will be protected for ten years after the first grant of marketing authorization in all Member States, and can be extended for an additional year if a further innovative indication has been authorized for that product, based on pre-clinical and clinical trials filed by the innovator that show a significant clinical benefit in comparison to the existing therapies. Approval of biosimilars in Europe follows the same process. However, biosimilars usually have to be approved through the centralized procedure because they are manufactured using recombinant DNA technology.

The regulatory pathway for the approval of a biosimilar product in the US was established under the Biologics Price Competition and Innovation Act (BPCIA), signed into law in March 2010. Under the BPCIA, a biosimilar must be highly similar with no clinically meaningful differences compared to the reference product. Approval of a biosimilar in the US requires the submission of a BLA to the FDA, including an assessment of immunogenicity, and pharmacokinetics or pharmacodynamics. The BLA for a biosimilar can be submitted four years after the initial approval of the reference biologic, but can only be approved 12 years after the initial approval of the reference biologic. This pathway is still new and some aspects are untried, controversial and subject to litigation.

Intellectual Property

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

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

VACCINES

Our Vaccines Division researches, develops, manufactures, distributes and sells human vaccines worldwide. Its products include meningococcal, influenza, pediatric, adult and travel vaccines. On April 22, 2014, Novartis announced that it had reached definitive agreements with GSK on a set of inter-conditional transactions that, if completed, would impact our Vaccines Division. As part of these transactions, Novartis agreed to divest Vaccines to GSK, excluding its influenza vaccines business, for up to $7.1 billion, consisting of $5.25 billion upfront and up to $1.8 billion in milestones, plus royalties. These transactions are expected to close in the first half of 2015. In October 2014, Novartis announced that it had reached a definitive agreement with the Australian based company CSL Limited to acquire its influenza vaccines business for $275 million. The sale of the influenza vaccines business is expected to close in the second half of 2015. The proposed transactions with GSK and CSL are subject to closing conditions and regulatory approvals. Following these transactions, we will retain certain intellectual property rights and related other revenues from the Vaccines Division, which are now reported under Corporate activities. Prior to the January 9, 2014 completion of the divestment of the blood transfusion

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diagnostics unit to Grifols S.A. for approximately $1.7 billion in cash, the division was known as Vaccines and Diagnostics. Diagnostics researched, developed, distributed and sold blood testing products. As of December 31, 2014, the Vaccines Division employed 6,491 full-time equivalent associates worldwide in more than 40 countries. In 2014, the Vaccines Division had consolidated net sales of $1.5 billion representing 3% of total Group net sales.

The Vaccines Division's products include meningococcal, influenza, pediatric, adult and travel vaccines, and our current product portfolio includes more than 16 marketed products. In addition, the division's development portfolio includes nine potential new products in Phase II and Phase III clinical trials and in various stages of registration.

Meningococcal disease causes approximately 50,000 deaths a year globally. The majority of infections are caused by five serogroups A, B, C, W-135 and Y and given that the distribution of these strains varies greatly over time and location, we are working to develop and deliver meningitis vaccines that offer broad coverage in order to help protect all age groups at risk.

Bexsero, the Novartis Meningococcal Group B Vaccine (rDNA, component, adsorbed), is a broad coverage vaccine available to help protect all age groups, including infants, against meningococcal disease caused by serogroup B (meningitis B). In 2013, *Bexsero* received EU approval. Since then, it has received regulatory approval in the US, Australia, Canada and Chile. To date, Bexsero has been approved in 37 countries. The US approval in January 2015 followed receipt of a Breakthrough Therapy designation from the FDA in April 2014, the commencement of a rolling submission of a BLA to the FDA for marketing approval of *Bexsero* to help protect individuals aged 10 through 25 years old from meningitis B, and the grant by FDA of priority review.

In 2013, *Bexsero* was launched privately in the UK, Germany, France and Ireland, with additional launches in Australia, Canada and several European countries since then. In 2014, *Bexsero* received recommendations for use in the National Immunization Programs (NIP) in the UK and Australia. *Bexsero* is currently under regulatory review in Argentina.

Menveo (MenACWY-CRM), a quadrivalent conjugate vaccine for the prevention of invasive meningococcal disease caused by the A, C, Y and W-135 serogroups of the bacteria, was approved in 2010 in the US for use in individuals 11-55 years old and in the EU for individuals 11 years and older. It is now approved in more than 60 countries. In 2011, *Menveo* gained approval for use in individuals 2-10 years of age in the US, and in 2012 gained approval in the EU for individuals 2 years and older. In 2013, the FDA expanded the approval of *Menveo* for the prevention of meningococcal disease in infants and toddlers from two months of age. With this expanded indication, pediatricians in the US can offer a single vaccine to help protect infants as young as two months of age, children and adolescents against four of the five most common serogroups that cause meningococcal disease.

Influenza vaccines are currently the division's largest franchise, and we are among the world's largest producers of influenza vaccine. Influenza vaccination is one of the most effective public health interventions, sparing millions of people from complications including death that can be caused by this infectious disease. In September 2013, Novartis began US shipments of *Flucelvax* [Influenza Virus Vaccine], the first cell-culture derived influenza vaccine approved in the US, to help protect adults 18 years of age and older against seasonal influenza. Cell-culture technology marks the most significant advancement in influenza vaccine manufacturing in the US in more than 40 years and is an alternative to traditional egg-based production. *Flucelvax* does not contain any preservatives, such as thimerosal, or antibiotics.

In June 2014, Novartis announced that the FDA had licensed its production facility in Holly Springs, North Carolina for the commercial production of seasonal and pandemic influenza vaccines developed using cell-culture technology. This is the first US facility of its kind and has the capacity to ramp up production in the event of an influenza pandemic. Following this site approval, *Flucelvax* was produced in the US and shipped for the first time for vaccination for the 2014-2015 season.

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In July 2014, Novartis became the first manufacturer to begin annual shipment of its seasonal influenza vaccines to the US market for the 2014-2015 influenza season. We have shipped more than 70 million doses of our seasonal influenza vaccines, including *Flucelvax* and *Fluvirin*, globally for the 2014-2015 influenza season, and at least 43 million of these doses went to US customers.

Young children and older adults are among the most vulnerable to influenza. *Fluad*, our adjuvanted seasonal influenza vaccine, has been approved for more than a decade in Europe to enhance the immune response in adults ages 65 and older, helping to overcome their naturally occurring immune vulnerability. In addition, we submitted for approval of *Fluad* for adults 65 years of age and older in the United States, and received approval for *Fluad Pediatric* for use in children six months to two years of age in Canada in November 2014.

Novartis has been awarded various contracts by the US Department of Health and Human Services (HHS), including a (pre)pandemic preparedness contract and an Advanced Development and Manufacturing (ADM) Center contract. Under the terms of the ADM contract, our production facility in Holly Springs, North Carolina provides late-stage development and manufacturing expertise and capabilities to support HHS-driven projects, including development of new biodefense agents and rapid manufacturing response in the event of a public health emergency. The (pre)pandemic preparedness contract was used to support activities initiated by Novartis to develop a new vaccine against H7N9, a strain of avian influenza that emerged in China in early 2013. Following positive trial results for the vaccine, the US government ordered a large supply of the vaccine for stockpiling that was delivered at the end of 2013. This was in advance of a sharp increase in the number of H7N9 cases in China that were associated with a second wave of the outbreak. In addition, Novartis remains dedicated to working with the World Health Organization and other stakeholders to support global pandemic preparedness, including affordable and equitable access to pandemic vaccines for developing countries.

In 2012, Novartis informed the WHO and other public health partners that it would cease oral polio vaccine (OPV) manufacturing by 2013. Novartis produced and delivered oral polio vaccines to UNICEF, PAHO and individual countries in 2013, and supply commitments for 2013 were fulfilled as contracted. Novartis has been proud to have provided a significant proportion of the global supply of OPV for more than 20 years and is a longtime supporter of the Global Polio Eradication Initiative.

Vaccines Division Products

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

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Selected Marketed Products

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

(1) In collaboration with Valneva.

(2) In collaboration with Crucell.

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Selected Products in Development

Project/product	Common name	Vaccine Type	Planned submission dates/Current phase
Acellular Pertussis combination	Tdap vaccine	Pediatric	≥2015/I
aQIVpediatric	Seasonal influenza vaccine	Seasonal Influenza	≥2015/III
C. difficile[1]	*C. difficile* vaccine	Hospital Infections	≥2015/I
Cell culture QIV	Seasonal influenza vaccine	Seasonal Influenza	≥2015/III
Fluad US	Seasonal influenza vaccine	Seasonal Influenza	2014/Submission[2]
Flucelvax age 4+ US	Seasonal influenza vaccine	Seasonal Influenza	2014/Submission
Group B streptococcus	Group B *streptococcus* vaccine	Maternal	≥2015/II
H5N1 influenza cell culture vaccine[3]	Pandemic influenza vaccine	Pandemic	≥2015/II
H7N9[3]	H7N9 vaccine	Pandemic Influenza	≥2015/Not applicable
Human immunodeficiency virus (HIV)[4]	HIV vaccine	HIV	≥2015/I
MenABCWY	Meningococcal A, B, C, W and Y vaccine	Meningitis	≥2015/II
P. aeruginosa[1]	*P. aeruginosa* vaccine	Hospital Infections	≥2015/II
S. aureus	*S. aureus* vaccine	Hospital Infections	≥2015/I

(1) Collaboration with Valneva.

(2) Submission pending acceptance by FDA.

(3) Collaboration with United States Department of Health and Human Services.

(4) Collaboration with United States National Institutes of Health.

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Principal Markets

The principal markets for our Vaccines Division include the US and Europe. The following table sets forth the aggregate 2014 net sales of the Vaccines Division by region:

Vaccines	2014 Net Sales to third parties	
	$ millions	%
Europe	549	36
United States	516	34
Asia, Africa, Australasia	248	16
Canada and Latin America	224	14
Total	**1,537**	**100**

	$ millions	%
Established Markets*	1,112	72
Emerging Growth Markets*	425	28
Total	**1,537**	**100**

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

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

Research and Development

In 2014, the Vaccines Division expensed $0.5 billion (on a core basis $0.5 billion) in research and development, which amounted to 36% of the division's net sales. The Vaccines Division expensed $0.5 billion (on a core basis $0.5 billion) and $0.5 billion (on a core basis $0.4 billion) in research and development in 2013 and 2012 respectively.

While research and development costs for vaccines traditionally have not been as high as for pharmaceuticals, a robust clinical program including Phase I to Phase III must be performed by the manufacturer to obtain a license for commercialization. See " Pharmaceuticals Compounds in Development" and " Pharmaceuticals Research and Development." At each step, there is a substantial risk that we will not achieve our goals. In such an event, we may decide or be required to abandon a product or program in which we have made a substantial investment.

Production

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

We manufacture our vaccines products at facilities in Europe, the US and Asia. Our principal production facilities are located in Liverpool, UK; Marburg, Germany; Siena and Rosia, Italy;

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Ankleshwar, India; and Holly Springs, North Carolina. We continue to invest and upgrade our existing sites to ensure that previously initiated remediation efforts are completed and meet quality standards.

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

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

Marketing and Sales

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

Competition

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

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

Regulation

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

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Intellectual Property

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

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

CONSUMER HEALTH

Consumer Health is a leader in the research, development, manufacturing and marketing of a wide range of competitively differentiated products that restore, maintain or improve the health and well-being of consumers. The business of Consumer Health is conducted by a number of affiliated companies throughout the world. In 2014, Consumer Health consisted of the OTC (over-the-counter medicines) Division and the Animal Health Division.

On April 22, 2014, Novartis announced that it had reached definitive agreements with GSK and Lilly intended to transform our portfolio of businesses, including Consumer Health. As part of a set of inter-conditional transactions with GSK, Novartis agreed to create a joint venture with GSK in consumer healthcare by combining our OTC Division with the GSK consumer healthcare business, of which we would own 36.5% and have four of eleven seats on the board of the joint venture. We will also have customary minority rights and exit rights under a pre-defined, market-based pricing mechanism. The transactions with GSK are subject to closing conditions and regulatory approval, and are expected to close in the first half of 2015. We also agreed to divest our Animal Health Division to Lilly for approximately $5.4 billion, which was completed on January 1, 2015.

Consumer Health now consists only of the OTC Division.

Prior to the divestment of our Animal Health Division to Lilly, OTC and Animal Health each had its own research, development, manufacturing, distribution and selling capabilities. However, neither division was material enough to the Group to be separately disclosed as a segment. As of December 31, 2014, the affiliates of Consumer Health employed 9,020 full-time equivalent associates worldwide. Following the January 1, 2015 completion of the divestment of Animal Health, the affiliates of OTC employed 6,070 full-time equivalent associates worldwide. In 2014, the affiliates of Consumer Health achieved consolidated net sales of $4.3 billion, which represented 7% of the Group's total net sales.

OTC places considerable emphasis on the development of strong, consumer-oriented and trustworthy brands. To deliver accelerated sales growth and to achieve leadership positions in the fields in which we compete, OTC gives voice to the consumer and helps consumers to determine their needs and desires. The success of our OTC Division depends upon its ability to anticipate and meet the needs of consumers and health professionals worldwide.

Our OTC Division is a leader in offering products designed for self-care and prevention of common medical conditions and ailments to enhance people's overall health and well-being. The business of OTC is conducted by a number of affiliated companies in more than 50 countries. The OTC business focuses on a group of strategic global brands in leading product categories that include treatments for cough/cold/respiratory ailments (e.g., *Theraflu* and *Otrivin*) and pain relief (e.g., *Excedrin* and over-the-counter

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Voltaren), as well as products for digestive health (e.g., *Benefiber* and *Prevacid24HR*), dermatology (e.g., *Lamisil* and *Fenistil*), and smoking cessation (*Nicotinell*).

Prior to its January 1, 2015 divestment to Lilly, Animal Health offered products and services to save, prolong and improve animal lives, focusing on both companion and farm animals (including cultivated fish).

Principal Markets

The principal markets for Consumer Health are the US and Europe. The following table sets forth the aggregate 2014 net sales of Consumer Health by region:

Consumer Health	**2014 Net Sales to third parties**	
	$ millions	**%**
Europe	2,059	48
United States	940	22
Asia, Africa, Australasia	834	19
Canada and Latin America	446	11
Total net sales	**4,279**	**100**

	$ millions	**%**
Established Markets*	2,798	65
Emerging Growth Markets*	1,481	35
Total net sales	**4,279**	**100**

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

Sales of our OTC Division are marked by a high degree of seasonality, with our cough, cold and respiratory brands significantly affected by the timing and severity of the annual cold and flu and allergy seasons. Sales of most of our other products are not subject to material changes in seasonal demand.

Production

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

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

We generally obtain our raw materials, intermediates and active ingredients from suppliers around the world. The raw materials, intermediates and active ingredients we purchase are generally subject to market price fluctuations. We seek to avoid these fluctuations, where possible, through the use of long-term supply contracts. We also proactively monitor markets and developments that could have an adverse

effect on the supply of essential materials. All raw materials we purchase must comply with our quality standards.

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The OTC facility located at Lincoln, Nebraska manufactures products in solid dose and powder form for the *Excedrin* and *Theraflu* OTC brands as well as *Sentinel*, an Animal Health brand. From 2011 until 2013, we suspended operations and shipments from this facility in order to accelerate maintenance and other improvement activities at the site. During this process, production of certain products previously made at Lincoln was out-sourced, while other products were discontinued. We also recalled certain OTC Division products that were produced at this facility. During 2013, we resumed commercial production and shipping of *Sentinel* and *Excedrin* from the Lincoln facility. In July 2014, we resumed shipment of *Theraflu* to the US market from Lincoln. We have invested considerable resources to remediate issues at the Lincoln site, and during 2014, the facility substantially returned to routine operational procedures. However, as of the date of this Form 20-F it is not possible to determine when the plant will resume full production. As a result of the activities at Lincoln, Consumer Health experienced significant supply interruptions, and there can be no assurance that supply will not be interrupted again in the future as a result of unforeseen circumstances.

In January 2015, we announced that we will close our manufacturing site located at Humacao, Puerto Rico in phases by early 2019. The Humacao facility currently manufactures and packages *Gas-X* and *Ex-Lax* products, and also packages certain other products including *Prevacid*, *Habitrol*, and *Transderm Scop*.

The manufacture of our products is complex and heavily regulated, which means that supply is never guaranteed. If we or our third-party suppliers fail to comply fully with regulations, this could result in additional product recalls or other shutdowns or disruptions to our production activities. In addition, we may rely on a single source of supply for some of our products and raw materials. We have implemented a global manufacturing strategy to maximize business continuity in case of business interruptions or other unforeseen catastrophic events. However, there can be no guarantee that we will be able to successfully manage such issues when they arise.

Marketing and Sales

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

Competition

The global market for products of the type sold by Consumer Health is highly competitive, and we compete against other major international corporations with substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development. Our branded OTC products compete against "store brand" products that are made with the same active ingredients as ours, but which may be sold at a lower price. In addition, the recent trend toward consolidation in the industry may result in even more intense competition.

Research and Development

At OTC, our Research and Development organization pursues science-based, consumer benefit-driven innovation. The focus of our research and development activities is primarily in the areas of pain relief and cough/cold/respiratory treatments, as well as potential new therapeutic categories for the business. The development of line extensions to leverage the value of our brands is of high importance. These line extensions can take many forms, including more consumer-friendly packaging. OTC also works

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closely with the Pharmaceuticals Division to evaluate appropriate products that can be switched from prescription to OTC status.

In 2014, Consumer Health expensed $0.3 billion (on a core basis $0.3 billion) in research and development, which amounted to 7% of the division's net sales. Consumer Health expensed $0.3 billion (on a core basis $0.3 billion) and $0.3 billion (on a core basis $0.3 billion) in research and development in 2013 and 2012 respectively.

Regulation

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

Intellectual Property

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

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

However, our OTC Division primarily sells products which are not currently covered by patents. Some of these products have never been patent-protected and others have lost protection due to patent expiry.

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4.C Organizational Structure

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

4.D Property, Plants and Equipment

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

We generally own our facilities. However, some sites are leased under long-term leases. Some of our principal facilities are subject to mortgages and other security interests granted to secure indebtedness to certain financial institutions.

For a discussion of our manufacturing facilities, see " Item 4.B Business Overview Pharmaceuticals Production," " Alcon Production," " Sandoz Production," " Vaccines Production," and " Consumer Health Production." The following table sets forth our major headquarters and most significant production and research and development facilities by division.

Location/Division	Size of Site (in square meters)	Major Activity
Major facilities:		
Pharmaceuticals		
East Hanover, NJ	400,000	Division US headquarters, research and development
Basel, Switzerland St. Johann	200,000	Global Group headquarters, global division headquarters, research and development, production of drug substances and drug intermediates
Stein, Switzerland	130,300	Production of sterile vials, pre-filled syringes and ampoules, and of inhalation capsules, tablets and transdermals, and of active pharmaceutical ingredients
Cambridge, MA	65,000	Global NIBR headquarters, research and development
Grimsby, UK	64,000	Production of drug substances and drug intermediates
Ringaskiddy, Ireland	60,000	Production of drug substances and drug intermediates
Basel, Switzerland Schweizerhalle	31,700	Production of drug substances and drug intermediates

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Location/Division	Size of Site (in square meters)	Major Activity
Torre, Italy	30,690	Production of tablets and capsules
Singapore	29,000	Production of bulk tablets
Barbera, Spain	26,380	Production of tablets, capsules and inhalation products
Wehr, Germany	24,000	Production of tablets, creams and ointments
Shanghai, China	14,200	Research and development
Morris Plains, NJ	14,000	Production of personalized medicine
Alcon		
Fort Worth, Texas	252,800	Division headquarters, production, research and development for Ophthalmic Pharmaceuticals, Vision Care, Surgical
Johns Creek, Georgia	73,400	Production, research and development for Vision Care
Grosswallstadt, Germany	72,500	Production, research and development for Vision Care
Puurs, Belgium	55,000	Production for Ophthalmic Pharmaceuticals, Surgical
Houston, Texas	36,300	Production for Surgical
Huntington, West Virginia	24,600	Production for Surgical
Irvine, California	20,700	Production for Surgical
Sandoz		
Kundl and Schaftenau, Austria	480,000	Production of biotech products, anti-infectives, active drug substances, product development
Ljubljana, Slovenia	120,000	Production of broad range of finished solid and sterile dosage forms
Barleben, Germany	340,000	Production of broad range of finished dosage forms

Holzkirchen, Germany	72,300	Division headquarters, production of oral films, transdermal delivery systems, matrix patches, product development

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Location/Division	Size of Site (in square meters)	Major Activity
Rudolstadt, Germany	37,000	Development and production of respiratory technologies and ophthalmics
Stryków, Poland	20,000	Production of broad range of bulk oral solid forms
Princeton, NJ	14,300	Division US headquarters
Vaccines		
Siena/Rosia, Italy	110,000	Production, research and development for vaccines and bacteriology
Marburg, Germany	80,000	Production, research and development for vaccines and adjuvant, quality control for all vaccines products
Hangzhou, China	50,800	Production of vaccines
Holly Springs, NC	50,000	Production, research and development of vaccines and adjuvant
Liverpool, UK	26,000	Production of vaccines
Ankleshwar, India	11,000	Production of vaccines
Cambridge, MA	9,000	Division headquarters, virology research
Consumer Health OTC		
Lincoln, NE	48,000	Production of solids and powders, research and development
Jamshoro, Pakistan	24,000	Production of solids, semi-solids and liquids
Nyon, Switzerland	15,000	Production of semi-solids and liquids, research and development
Parsippany, NJ	14,000	Division headquarters
Humacao, Puerto Rico	13,000	Production of solids
Hyderabad, India	3,000	Research and development

In 2010, we announced a Group-wide review of our manufacturing footprint. In 2014, and continuing into 2015, we continued to optimize our manufacturing footprint, bringing the total number of production sites that have been or are in the process of being restructured, exited or divested to 24. This has and is expected to enable us to reduce excess capacity and to shift strategic products to technology competence centers. We have recorded charges related to restructuring and exits, impairment charges and inventory write-offs of $183 million in 2014, bringing the total charges to $698 million since the program began. As

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part of this initiative we announced in 2014 the closing of the pharmaceuticals manufacturing site in Suffern, New York and the planned divestment of our pharmaceutical manufacturing site in Taboão da Serra, Brazil. Further, we announced the relocation of our *LenSx* laser manufacturing operations in Aliso Viejo, California to our Alcon Division's Surgical manufacturing site in Irvine, California.

Our St. Johann site in Basel, Switzerland, is our largest research and development site as well as the headquarters for the Group and for the Pharmaceuticals Division. A project was started in 2001, known as "Campus," with the aim of transforming the site into a center of knowledge, innovation and encounter with a primary emphasis on international corporate functions and research activities. At that time, changes needed to be made to the site, since it had originally been designed primarily for pharmaceuticals production, but Research and Development had come to account for a greater proportion of our activities there. The Campus project is progressing as planned. By the end of 2014, 15 new buildings had begun operations, seven of them laboratory buildings. Two further buildings are in the construction phase. These buildings are scheduled to open at the beginning of 2015. The current phase of the long term redevelopment of our St. Johann site is expected to be completed in 2015. In addition, the Novartis Board of Directors has approved planning for the next phase of the campus extension after 2015 in line with the overall plan for the site. A large laboratory building is planned for the northern end of the site. An architect has been commissioned to draw up plans for this building. In October 2014, the Basel "Grand Council" approved the second part of a high-rise building zone at the St. Johann site, which will allow us to plan a third high-rise building on the site. Through December 31, 2014, the total amount paid and committed to be paid on the Campus project is equivalent to $2.2 billion. Novartis expects to have spent more than the equivalent of $2.2 billion on Campus and the relocation of production facilities to other sites in the Basel region through 2015. We intend to fund these expenditures from internally generated resources.

In 2007, NIBR opened a start-up facility for our new R&D center in Shanghai, China (CNIBR). In 2008, we broke ground on Phase 1 of a new facility that was originally to be home to approximately 400 R&D scientists and approximately 400 other Pharmaceuticals Division personnel. In 2009, we announced that we would expand the scope of the site and invest $1 billion over the next five years to increase the size of our operations in Shanghai. Based on a re-evaluation of the site conducted in 2010, the current Phase 1 has been extended by two buildings to fulfill the requirements for the cross-divisional Shanghai campus to house 800 offices and 400 laboratory work places. As of December 31, 2014 the basement is completed, site infrastructure is tested and commissioning is in progress. In addition, the superstructures for the above ground buildings are completed, façade work is progressing, and for the majority of the buildings near completion, fit out work, testing and commissioning are underway. Through December 31, 2014, the total amount paid and committed to be paid on the CNIBR Project is $809 million.

In 2010, we announced that we would build new laboratory and office space for NIBR in Cambridge, Massachusetts on an area of land close to the existing NIBR research facilities on Massachusetts Avenue. In 2011 we finalized design plans for the new buildings, received necessary zoning changes from the City of Cambridge and began preparing the site for construction. Construction began on the site in April 2012, and as of the end of 2014, the façades were complete and work inside the buildings was underway. Through December 31, 2014, the total amount paid and committed to be paid on the NIBR Project is $743 million.

In 2010, we commenced a construction project on our Pharmaceuticals Division campus in East Hanover, New Jersey. It involved construction of three new office buildings, a parking garage, and upgrades to the site entrances. The purpose of the project was to consolidate US Pharmaceuticals Division personnel on one site to drive innovation, collaboration and productivity. The consolidation is also expected to achieve long-term cost savings resulting from the elimination of off-campus leases. The project was completed in March 2014. The facilities are operational and occupied and the off-campus leases have been terminated. The total amount paid and committed to be paid on this project was $557 million.

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During 2012, the Pharmaceuticals Division commenced a series of projects in which we expect to invest over $350 million over five years. These projects are in the following three areas: implementation of a serialization product tracking program across its pharmaceutical operations network, providing a health, safety and environment / Good Manufacturing Practices upgrade for its milling and blending center at Stein, Switzerland, and for the upgrade of change control systems.

In the second quarter of 2012, Novartis announced the construction of a new state-of-the-art production facility to produce solid dosage form medicines for the Pharmaceuticals Division in Stein, Switzerland. We expect our investment in this facility to exceed $518 million. The new facility is planned to replace an older facility. Stein is planned to be a technological competence center for both sterile and solid dosage form drugs, while Novartis plans to expand the site's strategic role as a key platform for global launches of new pharmaceutical products. Through December 31, 2014, the total amount paid and committed to be paid on this project is $480 million.

In the fourth quarter of 2012, we announced the planned construction of a new state-of-the-art biotechnology production site in Singapore with an investment valued at over $500 million. The new facility will focus on drug substance manufacturing based on cell culture technology. Groundbreaking happened in February 2013 and construction is underway. The site is expected to be operational in 2016. It will be co-located with the pharmaceutical production site based in Tuas, Singapore. In the future, Singapore is expected to be a technological competence center for both biotechnology and pharmaceutical manufacturing at Novartis. Through December 31, 2014, the total amount paid and committed to be paid on this project is $342 million.

In December 2012, we acquired a 16,000 square meter FDA-approved manufacturing facility in Morris Plains, New Jersey, from Dendreon Corporation for $43 million. In particular, we purchased all fixed assets at the site, including all equipment, machinery, utilities, and cell therapy related plant infrastructure, while the land and building will continue to be leased from a third party. The facility, and the former Dendreon personnel whom we retained, will support both clinical and commercial production of potential new products and therapies that emerge from the Novartis-University of Pennsylvania collaboration announced in August 2012, including CTL019. The facility space and infrastructure could also accommodate future chimeric antigen receptor production activities, in addition to CTL019. Between January 2013 and the end of 2014, we have invested $15 million in the site, primarily on equipment for manufacturing and establishing new IT systems such as SAP. Through December 31, 2014, the total amount paid and committed to be paid on this project is $18 million.

In 2008, the Vaccines Division broke ground on a new rabies and tick-borne encephalitis manufacturing facility in Marburg, Germany, for which construction is now complete. In the first half of 2014, the EU and FDA approved the rabies antigen manufactured at the Marburg facility, meaning that *RabAvert* produced at the site can now be marketed in the EU and US. We are also now licensed to market *Encepur* manufactured at the site in the EU. Spending on this project was completed in 2014.

In 2009, the Vaccines Division opened the division's new cell culture-based influenza vaccine manufacturing site in Holly Springs, North Carolina. In June 2014, the FDA licensed the site for the production of cell-culture influenza vaccines. It is the first US facility of its kind and is approved for commercial production of seasonal and pre-pandemic influenza vaccines, with the capacity to significantly increase production in the event of an influenza pandemic. As of December 31, 2014, the total amount spent on the project was $597 million, net of grants reimbursed by the US government. This facility is part of the planned divestment of our influenza vaccines business to CSL. As described further in "Item 18. Financial Statements," upon announcement of this planned divestment we recorded a total impairment charge of $1.071 billion which included the full write off of the investment in the Holly Springs facility.

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In 2014, the Alcon Division completed expansion of its Johns Creek, Georgia facility for contact lens manufacturing. The expansion added 6,500 square meters to the existing facility. With this expansion complete, the site began commercial production of *Dailies Total1* contact lenses in the fourth quarter of 2014. The total cost of this project was $268 million.

Environmental Matters

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

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

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

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

5.A Operating Results

This operating and financial review should be read together with the Group's consolidated financial statements in this Annual Report, which have been prepared in accordance with IFRS as published by the IASB.

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 over-the-counter products.

On April 22, 2014, Novartis announced that it had reached definitive agreements with GSK and Lilly on a set of transactions intended to transform our portfolio of businesses.

In inter-conditional transactions with GSK, Novartis agreed to: (1) acquire GSK oncology products and certain related assets, and was granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines; (2) create a joint venture with GSK in consumer healthcare by combining the Novartis OTC Division with the GSK consumer healthcare business, of which Novartis would own 36.5% and would have four of eleven seats on the joint venture's Board; and (3) divest the Vaccines Division (excluding the influenza vaccines business) to GSK. In addition, Novartis agreed to divest the Animal Health Division to Lilly. The divestment of our Animal Health Division to Lilly was completed on January 1, 2015.

On October 26, 2014, Novartis announced that it had reached a definitive agreement with CSL Limited (CSL) of Australia to divest its influenza vaccines business for $275 million.

The transactions with GSK and CSL are subject to closing conditions and regulatory approvals. The transactions with GSK are expected to close in the first half of 2015, and the transaction with CSL is expected to close in the second half of 2015.

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The Group's wholly-owned businesses are organized into five global operating divisions, and we report our results in the following five segments. In addition, we separately report Corporate activities. Following the announcement of the transactions with GSK and Lilly, in order to comply with IFRS, Novartis has separated the Group's reported financial data for the current and prior year into "continuing" operations and "discontinuing" operations:

Continuing Operations:

- Pharmaceuticals: Innovative patent-protected prescription medicines
- Alcon: Surgical, ophthalmic pharmaceutical and vision care products
- Sandoz: Generic pharmaceuticals
- Corporate activities

Discontinuing Operations:

- Vaccines: Preventive human vaccines and the blood transfusion diagnostics unit, which was divested on January 9, 2014.
- Consumer Health: OTC (over-the-counter medicines) (following the January 1, 2015 completion of the divestment of our Animal Health Division to Lilly, the Consumer Health segment now consists only of the OTC Division)
- Corporate: certain transactional and other expenses related to the portfolio transformation

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

We separately report the financial results of our Corporate activities as part of our Continuing Operations. Income and expenses relating to Corporate include the costs of the Group headquarters and those of corporate coordination functions in major countries. In addition, Corporate includes other items of income and expense which are not attributable to specific segments such as certain expenses related to post-employment benefits, environmental remediation liabilities, charitable activities, donations and sponsorships.

Our divisions are supported by Novartis Business Services and the Novartis Institutes for BioMedical Research.

- Novartis Business Services (NBS) was launched in July 2014 with the transfer of over 7,000 associates, and organizational structures are being implemented to start operations in January 2015 as a shared services organization. NBS is designed to enhance profitability by harmonizing high-quality services at better price across the Group and Divisions. It covers approximately $6 billion in expenses, and synergies generated by the organization are expected to improve margin over time.
- The Novartis Institutes for BioMedical Research (NIBR) was created in 2003, and is headquartered in Cambridge, Massachusetts. More than 5,900 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, UK, Italy, Singapore and China. For more information about NIBR, see " Pharmaceuticals Research and Development Research program," below.

Novartis achieved net sales of $58.0 billion in 2014, while net income amounted to $10.7 billion. Research & Development expenditure in 2014 amounted to $9.9 billion ($9.6 billion excluding impairment and amortization charges). Of the Group's total net sales, $15.3 billion, or 26%, came from Emerging Growth Markets, and $42.6 billion, or 74%, came from Established Markets. Emerging Growth Markets

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

Headquartered in Basel, Switzerland, our Group companies employed 133,413 full-time equivalent associates as of December 31, 2014. Our products are available in approximately 180 countries around the world.

OPPORTUNITY AND RISK SUMMARY

Our financial results are affected, to varying degrees, by external factors. The aging of the global population and prevalence of behaviors that increase the risk of obesity and other chronic diseases is driving demand for treatments that Novartis provides, while the continued rise in healthcare spending causes customers to gravitate toward lower-cost treatment options which we produce at Sandoz and OTC. Advances in the fields of genomics and biotechnology and increasing use of connected medical devices and health information technology provide new opportunities for more tailored treatments to individual patients.

However, the loss of market exclusivity and the introduction of branded and generic competitors could significantly erode sales of our innovative products. Heightened regulatory requirements, the inherent complexity of our industry, and the risk of safety events increase our cost of doing business, and could lead to difficulties in bringing products to market and maintaining supply. The increasing trend of government investigations and litigations against healthcare companies, despite our best efforts to comply with local laws, could also have an adverse effect on our business and reputation.

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

RESULTS OF OPERATIONS

In evaluating the Group's performance, we consider not only the IFRS results, but also certain non-IFRS measures, including core results, constant currency results and adjusted 2013 results. These measures assist us in evaluating our ongoing performance from year to year and we believe this additional information is useful to investors in understanding our business.

The Group's core results exclude the amortization of intangible assets and impairment charges. They also exclude expenses relating to divestments, the integration of acquisitions and other income and expense items that are over a $25 million threshold that management deems exceptional. A reconciliation between IFRS results and core results, see " Core Results"below.

We present information about our revenue and other key figures relating to operating profit and net income in constant currencies (cc). We calculate constant currency revenue and operating profit by applying the prior-year average exchange rates to current financial data expressed in local currencies in order to estimate an elimination of the impact of foreign exchange rate movements.

Adjusted 2013 results are discussed below. In addition, these and other non-IFRS measures are explained in more detail, see " Non-IFRS Measures as defined by Novartis" below and are not intended to be substitutes for the equivalent measures of financial performance prepared in accordance with IFRS. These measures may differ from similarly titled non-IFRS measures of other companies.

2014 Compared to 2013

Group overview

The following table presents certain key figures for the Novartis Group, including net sales and net income and a comparison of those figures for 2014 against those for 2013. In addition, the table presents the same information adjusted to enable a comparison of our 2014 results against 2013 results excluding the results of our former blood transfusion diagnostics unit, which Novartis divested on January 9, 2014. No other adjustments are made to the 2013 figures. Novartis believes that this comparison will enhance investors' understanding of the performance of our ongoing business. For more information,

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see " Non-IFRS Measures as defined by Novartis 2013 Reconciliation of Group IFRS and core results excluding blood transfusion diagnostics unit".

Key figures

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies	excluding Diagnostics Year ended Dec 31, 2013	Change in $ % (excluding Diagnostics)[1]	Change in constant currencies % (excluding Diagnostics)[1]
	$ m	$ m	%	%	$ m		
Net sales to third parties	**57,996**	**57,920**	**0**	**2**	**57,355**	**1**	**3**
Other revenues	1,280	911	41	41	699	83	83
Cost of goods sold	(20,101)	(19,608)	(3)	(3)	(19,171)	(5)	(6)
Gross profit	**39,175**	**39,223**	**0**	**3**	**38,883**	**1**	**4**
Marketing & Sales	(14,189)	(14,549)	2	0	(14,504)	2	0
Research & Development	(9,943)	(9,852)	(1)	(1)	(9,823)	(1)	(1)
General & Administration	(3,047)	(3,060)	0	0	(3,039)	0	(1)
Other income	2,380	1,367	74	74	1,358	75	75
Other expense	(3,640)	(2,219)	(64)	(64)	(2,204)	(65)	(66)
Operating income	**10,736**	**10,910**	**(2)**	**5**	**10,671**	**1**	**7**
Return on net sales (%)	18.5	18.8			18.6		
Income from associated companies	1,920	600	220	220	600	220	220
Interest expense	(704)	(683)	(3)	(6)	(683)	(3)	(6)
Other financial income and expense	(31)	(92)	66	31	(92)	66	31
Income before taxes	**11,921**	**10,735**	**11**	**17**	**10,496**	**14**	**20**
Taxes	(1,641)	(1,443)	(14)	(20)	(1,352)	(21)	(28)
Net income	**10,280**	**9,292**	**11**	**17**	**9,144**	**12**	**19**
Attributable to:							
Shareholders of Novartis AG	*10,210*	*9,175*	*11*	*18*	*9,027*	*13*	*19*
Non-controlling interests	*70*	*117*	*(40)*	*(41)*	*117*	*(40)*	*(41)*
Basic earnings per share ($)	**4.21**	**3.76**	**12**	**18**	**3.70**	**14**	**20**
Free cash flow	**10,762**	**9,945**	**8**		**9,592**	**12**	

(1) Excluding the blood transfusion diagnostics unit divested on January 9, 2014.

Novartis delivered solid financial performance in 2014, driven by our continued success with growth products and expansion in emerging growth markets, which helped offset the effects of generic competition of approximately $2.4 billion. As a result, we achieved Group net sales of $58.0 billion, the same level as 2013 in reported terms, and up 2% in constant currencies (cc). Group operating income amounted to $10.7 billion (2%, +5% cc). Operating income margin was 18.5% of net sales. Group net income rose 11% (+17% cc) to $10.3 billion. Earnings per share (EPS) rose 12% (+18% cc) to $4.21. Free cash flow in 2014 increased by 8% to $10.8 billion, mainly due to higher cash flows from operating activities.

To help illustrate performance on a more comparable basis, we also provide comparisons against 2013 data excluding the results of the blood transfusion diagnostics unit, which was divested on January 9, 2014. Excluding the divested unit, Group net sales were up 3% (cc), operating income advanced 7% (cc), net income rose 19% (cc) and EPS was up 20% (cc).

In addition, to help investors track the underlying health of our business, we present our core results, which exclude the exceptional impact of significant disposals and acquisitions, as well as other significant exceptional items. Our core results also exclude sales and income from the divested blood transfusion diagnostics unit. Our core operating income in 2014 increased 3% (+8% cc) to $14.6 billion. Core

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operating income margin increased 0.5 percentage points to 25.2% of net sales, as our efforts to enhance productivity helped to offset 0.7 percentage points of negative impact from changing currency exchange rates. Core net income was $12.8 billion, up 3% (+8% cc), and core earnings per share rose 4% (+10% cc) to $5.23.

Growth

Across divisions, our portfolio of growth products and presence in emerging growth markets continued to fuel performance in 2014. Growth products comprise products launched in 2009 or later, or products with exclusivity until at least 2018 in key markets (EU, US, Japan) (except Sandoz, which includes only products launched in the last 24 months).

Sales of growth products increased 18% to $18.6 billion, or 32% of net sales. In the Pharmaceuticals Division, growth products accounted for 43% of net sales, up from 37% in 2013 demonstrating how we are rejuvenating our portfolio and mitigating the impact of patent expirations on key products.

Top-performing Pharmaceuticals products in 2014 included *Gilenya* ($2.5 billion, +30% cc), our oral therapy for multiple sclerosis; *Afinitor* ($1.6 billion, +22% cc), a treatment for several types of cancer including breast and kidney; and *Tasigna* ($1.5 billion, +24% cc), a treatment for chronic myeloid leukemia.

At Alcon, surgical equipment was a key growth driver, following the launch in late 2013 of the *Centurion* Vision System and continued growth of the *LenSx* femtosecond laser for cataract surgery. Disposable products for cataract and vitreoretinal surgery also showed strong growth.

In the Sandoz Division, biosimilars which are follow-on versions of complex biologic drugs made a strong contribution to growth, with sales rising 23% (cc) to $514 million globally.

In addition, efforts to expand our presence in emerging growth markets such as Asia, Africa and Latin America continued to show good results. Emerging growth markets comprise all markets except the US, Canada, Western Europe, Japan, Australia and New Zealand. Net sales in those markets rose 11% (cc) to $15.3 billion, led by China, up 15% (cc), and by Brazil, up 18% (cc).

Productivity

Novartis made solid progress in 2014 in generating synergies across divisions to improve productivity. Overall savings reached approximately $2.9 billion, exceeding our target. In 2014, we also created Novartis Business Services (NBS), a shared services organization designed to enhance profitability by harmonizing and simplifying the provision of services to the divisions. NBS is expected to play a key role in accelerating our productivity gains.

The most significant savings of $1.6 billion came from ongoing efforts in procurement to manage spending on goods and services across all our divisions. That represents 7% of the annual spending of $22 billion managed by the procurement organization.

An area where we made significant progress in 2014 was travel, where we reduced spending by about 23% across the company. We primarily achieved this by increasing the use of virtual meetings among Novartis colleagues, in lieu of travel. We aim to continue increasing the use of videoconferences and other technology for internal meetings to make these savings sustainable.

We also made strides in managing capital spending for equipment at manufacturing sites worldwide. In 2014, we began adopting standard technical requirements for machinery across our divisions. For instance, we now have uniform specifications for tablet presses, a common type of equipment previously purchased individually by each manufacturing site. This standardization enabled us to negotiate better prices from our supplier and will help reduce future costs related to such things as commissioning new equipment and maintenance.

Additionally, our multi-year plan begun in 2010 to optimize our global manufacturing network is on track. In 2014, we announced several further steps, including the closure of our pharmaceuticals manufacturing site in Suffern, New York, in the US and the planned sale of our pharmaceuticals

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manufacturing site in Taboão da Serra, Brazil bringing the total number of production sites that have been or are being restructured or divested to 24. These changes are helping us balance capacity, reducing it where no longer needed and adding new capacity for the products and technologies of the future.

We continued to find synergies to increase sales through our Customers First program, which delivered $1.6 billion in revenues in 2014, generating 2.8% of Group net sales. This program aims to serve our customers more effectively by ensuring they have access to a full range of Novartis products from all divisions.

Net Sales by Segment

The following table provides an overview of net sales to third parties by segment:

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Pharmaceuticals	**31,791**	**32,214**	**(1)**	**1**
Alcon	**10,827**	**10,496**	**3**	**6**
Sandoz	**9,562**	**9,159**	**4**	**7**
Continuing operations	**52,180**	**51,869**	**1**	**3**
Discontinuing operations[(1)]	5,816	6,051	**(4)**	**(1)**
Net sales	**57,996**	**57,920**	**0**	**2**

(1) Discontinuing operations are explained in more detail, see " Factors affecting comparability of year-on-year results of operations" and "Item 18. Financial Statements Notes 3 and 30".

Continuing Operations

Pharmaceuticals

Pharmaceuticals delivered net sales of $31.8 billion (1%, +1% in constant currencies, or cc) as strong sales of growth products countered the impact of greater generic competition for *Diovan* and other products, particularly in the US and Japan. Generic competition reduced sales by seven percentage points.

Growth products generated $13.7 billion of division net sales, growing 17% (cc) compared to last year. These products which include *Gilenya*, *Afinitor*, *Tasigna*, *Galvus*, *Lucentis*, *Xolair*, *Jakavi* and our portfolio of products for the treatment of chronic obstructive pulmonary disease (COPD) contributed 43% of division net sales, compared to 37% in 2013.

Sales in emerging growth markets increased 11% (cc) to $8.1 billion.

Oncology

Oncology sales rose 4% (+6% cc) to $11.7 billion, despite increased generic competition for *Zometa* ($264 million, 55% cc). By brand, growth was driven mainly by *Afinitor*, up 22% (cc) to $1.6 billion; *Tasigna*, up 24% (cc) to $1.5 billion; and *Jakavi*, up 72% (cc) to $279 million.

Primary Care

Sales in Primary Care, which includes mainly cardiovascular, metabolic and respiratory products amounted to $8.0 billion in 2014, down 12% (10% cc). Excluding older, established medicines such as *Diovan* ($2.3 billion, 32% cc), sales rose 13% (+16%) to $2.8 billion. The recently launched COPD portfolio, for example, which includes *Onbrez Breezhaler/Arcapta Neohaler*, *Seebri Breezhaler,* and *Ultibro Breezhaler,* grew 93% (cc) to $484 million. Other key products include the *Galvus* Group, up 6% (cc) to $1.2 billion; and *Xolair*, up 30% (cc) to $777 million.

Specialty Care

Sales in Specialty Care, which includes our Neuroscience, Integrated Hospital Care and Ophthalmics products, amounted to $10.1 billion. *Gilenya*, our oral multiple sclerosis therapy, grew 30% (cc) to $2.5 billion, with strong volume growth through new patient initiations in the US and elsewhere. Sales of *Lucentis*, for ocular conditions, rose 5% (cc) to $2.4 billion, driven by increased use in new indications beyond wet age-related macular degeneration.

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TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2014

Brands	Business franchise	Indication	Net sales in United States	Change in constant currencies	Net sales in Rest of world	Change in constant currencies	Total net sales	Change in $	Change in constant currencies
			$ m	%	$ m	%	$ m	%	%
Gleevec/Glivec	Oncology	Chronic myeloid leukemia	2,170	12	2,576	(5)	**4,746**	**1**	**2**
Gilenya	Neuroscience	Relapsing multiple sclerosis	1,190	16	1,287	45	**2,477**	**28**	**30**
Lucentis	Ophthalmics	Age-related macular degeneration			2,441	5	**2,441**	**2**	**5**
Diovan/Co Diovan	Primary Care	Hypertension	960	(43)	1,385	(22)	**2,345**	**(33)**	**(32)**
Sandostatin	Oncology	Acromegaly	751	6	899	6	**1,650**	**4**	**6**
Afinitor/Votubia	Oncology	Breast cancer	805	16	770	29	**1,575**	**20**	**22**
Tasigna	Oncology	Chronic myeloid leukemia	540	26	989	23	**1,529**	**21**	**24**
Exforge	Primary Care	Hypertension	284	(20)	1,112	4	**1,396**	**(4)**	**(2)**
Galvus	Primary Care	Diabetes			1,224	6	**1,224**	**2**	**6**
Exelon/Exelon **Patch**	Neuroscience	Alzheimer's disease	485	6	524	(6)	**1,009**	**(2)**	**(1)**
Exjade	Oncology	Iron chelator	307	16	619	1	**926**	**4**	**6**
Xolair[(1)]	Primary Care	Asthma			777	30	**777**	**27**	**30**
Neoral/Sandimmun	Integrated Hospital Care	Transplantation	55	(2)	629	(6)	**684**	**(9)**	**(6)**
Voltaren **(excl. other divisions)**	Established medicines	Inflammation/pain			632	(3)	**632**	**(6)**	**(3)**
Myfortic	Integrated Hospital Care	Transplantation	149	(45)	394	14	**543**	**(15)**	**(11)**
Ritalin/Focalin	Established medicines	Attention deficit/ hyperactivity disorder	327	(25)	165	8	**492**	**(17)**	**(16)**
Femara	Oncology	Breast cancer	27	42	353	0	**380**	**(1)**	**2**
Comtan/Stalevo	Neuroscience	Parkinson's disease	19	(42)	352	(1)	**371**	**(7)**	**(4)**
Tegretol	Established medicines	Epilepsy	82	19	264	1	**346**	**1**	**4**
Zortress/Certican	Integrated Hospital Care	Transplantation	60	88	267	28	**327**	**31**	**36**
Top 20 products total			**8,211**	**(3)**	**17,659**	**4**	**25,870**	**0**	**2**
Rest of portfolio			1,561	(13)	4,360	0	**5,921**	**(6)**	**(4)**
Total Division sales			**9,772**	**(5)**	**22,019**	**3**	**31,791**	**(1)**	**1**

(1) Net sales reflect *Xolair* sales for all indications (i.e. *Xolair* SAA and *Xolair* CSU, which are managed by the Integrated Hospital Care franchise).

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Gleevec/Glivec ($4.7 billion, +2% cc) sales grew slightly in 2014. *Gleevec/Glivec* is a treatment for adult patients with metastatic and/or unresectable KIT+ gastrointestinal stromal tumors (GIST), as an adjuvant treatment for certain adult patients following resection of KIT+ GIST, and as a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). Sales were driven mainly by the US, and more than compensated for the loss of patent exclusivity in some markets. In the US, Novartis Pharmaceuticals Corporation has settled its litigation with a subsidiary of Sun Pharmaceutical Industries Ltd. relating to Novartis patents covering the use of certain polymorphic forms of *Gleevec/Glivec*, which expire in 2019 (including pediatric exclusivity). The basic compound patent for *Gleevec/Glivec* expires in the US on July 4, 2015. As a result of the settlement, Novartis will permit Sun's subsidiary to market a generic version of *Gleevec/Glivec* in the US beginning on February 1, 2016.

Gilenya ($2.5 billion, +30% cc), the first once-daily oral therapy to treat relapsing forms of multiple sclerosis (MS), continued to outgrow the market, achieving double-digit growth in 2014 in recognition of strong trends towards oral treatments with higher efficacy. Growth was also fueled by an increasing acceptance of the role of high-efficacy treatments when used earlier in the course of the disease. *Gilenya* continues to see volume growth through new patient initiations in both the US and non-US markets. In the US, *Gilenya* is indicated for relapsing forms of MS. In the EU, *Gilenya* is indicated for adult patients with high disease activity despite treatment with at least one disease modifying agent, or rapidly evolving severe relapsing remitting MS. *Gilenya* is currently approved in over 80 countries around the world. *Gilenya* is licensed from Mitsubishi Tanabe Pharma.

Lucentis ($2.4 billion, +5% cc) saw volume growth driven by the uptake in non-Age-Related macular degeneration (AMD) indications (such as visual impairment due to diabetic macular edema; macular edema secondary to central and branch retinal vein occlusion; and choroidal neovascularization secondary to pathologic myopia). In addition, the *Lucentis* pre-filled syringe was successfully launched in all key European countries, as well as Japan and Australia. Non-AMD indications contributed 41% of *Lucentis* sales in 2014, compared to 27% for 2013, and became a blockbuster in Q4. Emerging growth markets contributed 18% of *Lucentis* sales versus 16% last year. Emerging growth markets comprise all markets except the US, Canada, Western Europe, Japan, Australia and New Zealand. At the same time, *Lucentis* sales in the wet AMD indication, impacted by competition, are stabilizing in some markets. *Lucentis* is the only anti-VEGF therapy licensed in most countries for the treatment of the following ocular indications: wet AMD, visual impairment due to diabetic macular edema, visual impairment due to macular edema secondary to retinal vein occlusion and secondary to branch retinal vein occlusion, and visual impairment due to choroidal neovascularization secondary to pathologic myopia (mCNV). *Lucentis* is approved in more than 100 countries to treat patients with the first four conditions, and in more than 70 countries for mCNV. Genentech/Roche holds the rights to *Lucentis* in the US.

Diovan Group ($2.3 billion, 32% cc), consisting of *Diovan* monotherapy and the combination product *Co-Diovan/Diovan* HCT, saw a continued sales decline worldwide due to generic competition in most markets, including the US (following July 7, 2014 *Diovan* monotherapy generic entry), many EU countries and Japan (generic entry in June 2014), compounded in Japan by the impact of issues related to investigator initiated trials. Sales continued to grow in Emerging Growth Markets, including China and selected countries in Latin America, Asia Pacific and Africa.

Sandostatin ($1.7 billion, +6% cc) continued to benefit from the increasing use of *Sandostatin LAR* (long acting release) in key markets. *Sandostatin* is a somatostatin analogue used to treat patients with acromegaly as well as neuroendocrine tumors (NET). In NET, it is used for both the treatment of patients with symptoms of carcinoid syndrome and those with advanced NET of the midgut or unknown primary tumor location (currently approved in 47 countries). An enhanced presentation of *Sandostatin LAR*, which includes an improved diluent, safety needle and vial adapter, has been approved in 58 countries, with additional filings underway.

Afinitor/Votubia ($1.6 billion, +22% cc) performance was driven by strong growth in the US, Japan and other markets. *Afinitor* is an oral inhibitor of the mTOR pathway approved for the treatment of

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patients with HR+/HER2 advanced breast cancer after failure with a non-steroidal aromatase inhibitor, for advanced renal cell carcinoma following vascular endothelial growth factor-targeted therapy and for the treatment of advanced pancreatic neuroendocrine tumors. *Afinitor* is also approved for subependymal giant cell astrocytoma (SEGA) and renal angiomyolipoma associated with tuberous sclerosis complex (TSC). Everolimus, the active ingredient in *Afinitor/Votubia*, is also available in more than 60 countries for the treatment of renal angiomyolipomas and/or SEGA associated with TSC, including as a dispersible tablet formulation in the US and EU for SEGA. Everolimus, the active ingredient in *Afinitor/Votubia*, is available under the trade names *Zortress/Certican* for use in other non-oncology indications and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Tasigna ($1.5 billion, +24% cc) performance was driven by strong growth in the US and other markets. *Tasigna* is a more effective, targeted therapy than *Gleevec/Glivec* for adult patients newly diagnosed with Ph+ CML in the chronic phase or for adult patients in the chronic or accelerated phase who are resistant or intolerant to at least one prior therapy including *Gleevec/Glivec*. It is currently approved as a first-line therapy for newly diagnosed patients with Ph+ CML in the chronic phase in more than 85 countries globally, including the US, EU, Japan and Switzerland, with additional submissions pending worldwide. *Tasigna* (nilotinib) is also approved in more than 110 countries as a second-line treatment for patients with Ph+ CML in chronic and/or accelerated phase who are resistant or intolerant to existing treatment, such as *Gleevec/Glivec*.

Exforge Group ($1.4 billion, 2% cc), includes two medicines approved for the treatment of hypertension*Exforge*, a single-pill combination of the angiotensin receptor blocker (ARB) valsartan and the calcium channel blocker amlodipine besylate; and *Exforge* HCT, a single pill combining an ARB (valsartan), calcium channel blocker (amlodipine) and a diuretic (hydrochlorothiazide). *Exforge* lost exclusivity in October 2014 and *Exforge* HCT in November 2014 in the US. Outside the US, *Exforge* continues to grow, with double-digit growth in China and a number of emerging growth markets. Emerging growth markets comprise all markets except the US, Canada, Western Europe, Japan, Australia and New Zealand. *Exforge* is now available in more than 100 countries. *Exforge* HCT is available in over 60 countries.

Galvus Group ($1.2 billion, +6% cc), which includes *Galvus*, an oral treatment for type 2 diabetes, and *Eucreas*, a single-pill combination of vildagliptin (the active ingredient in *Galvus*) and metformin, continued to grow in 2014 despite the distribution stop in the German market on July 1, 2014. Sales for the first six months of 2014 in Germany were $57 million. *Galvus* delivered a solid performance with strong growth coming from emerging markets. The focus for *Galvus* remains on patients whose diabetes remains uncontrolled on metformin, as well as on an expansion of usage in new patient segments based on new indications. *Galvus* Group is currently approved in more than 120 countries.

Exelon/Exelon Patch ($1.0 billion, 1% cc) sales declined slightly, due to generic competition for*Exelon* Patch in the EU offsetting a solid performance for *Exelon* Patch in the US. *Exelon* Patch is approved for the treatment of mild-to-moderate Alzheimer's disease dementia (AD) in more than 90 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. *Exelon* Patch is also indicated for the treatment of patients with severe AD in 11 countries, including the US. In Europe, the high-dose patch (15 cm^2) for mild-to-moderately severe AD was launched in several markets in 2013.

Exjade ($926 million, +6% cc), a once-daily oral therapy for chronic transfusional iron overload first approved in 2005 and now approved in more than 100 countries, saw sales increases in the US and Asia. *Exjade* is also approved for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia in more than 70 countries.

Xolair ($777 million, +30% cc), a biologic drug for appropriate patients with severe persistent allergic asthma in Europe and moderate-to-severe persistent allergic asthma in the US, is currently approved in more than 90 countries as a treatment for moderate-to-severe or severe persistent allergic asthma. Its

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sales continued to grow strongly in Canada, Europe and Latin America. *Xolair* is also approved in the EU, Switzerland and 35 other countries as a treatment for chronic spontaneous urticaria, also known as chronic idiopathic urticaria, for which it is approved in the US and now Canada and Australia. Novartis co-promotes *Xolair* with Genentech/Roche in the US and shares a portion of the operating income, but does not book US sales.

Neoral/Sandimmun ($684 million, 6% cc), a micro-emulsion formulation of cyclosporine, 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. Additionally, it is 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.

Voltaren/Cataflam ($632 million, 3% cc), 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 registered 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 Sandoz Division markets generic versions of *Voltaren*, our Alcon Division markets *Voltaren* for ophthalmic indications, and our OTC Division markets low-dose oral forms and the topical therapy of *Voltaren* as over-the-counter products. Total sales across all divisions of *Voltaren/Cataflam* (diclofenac) amounted to $1.6 billion in 2014 and grew 7.5% in constant currencies against the prior year.

Myfortic ($543 million, 11% cc), a transplantation medicine, is available in more than 90 countries to prevent organ rejection in adult kidney transplant patients. It has experienced a sales decline after the expected launch of generic competition in the US in early 2014. *Myfortic* continues to grow in geographies without generic competition.

Ritalin/Focalin ($492 million, 16% cc) is a treatment for attention deficit hyperactivity disorder (ADHD) in children*Ritalin* and *Ritalin LA* are available in more than 70 and 30 countries, respectively, and are also indicated for narcolepsy. *Ritalin LA* has been granted in 2014 the "adult ADHD indication" in several countries (16 to date). *Focalin* and *Focalin* XR are available in the US and *Focalin* XR is additionally indicated for adults. *Focalin* XR is also approved in Switzerland. *Ritalin* Immediate Release has generic competition in most countries. Some strengths of *Ritalin* and *Focalin* are subject to generic competition in the US.

Femara ($380 million, +2% cc), a treatment for early stage and advanced breast cancer in postmenopausal women, experienced steady sales despite multiple generic entries in the US, Europe and other key markets.

Comtan/Stalevo ($371 million, 4% cc), indicated for the treatment of Parkinson's disease, saw sales decline in 2014 due to generic competition in some markets. *Stalevo* (carbidopa, levodopa and entacapone) is indicated for certain Parkinson's disease patients who experience end-of-dose motor fluctuations, known as "wearing off." In July 2014, Stalevo was granted marketing authorization for the treatment of Parkinson's disease in Japan. *Stalevo* is available in more than 90 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 42 countries. Both products are marketed by Novartis under a licensing agreement with the Orion Corporation.

Tegretol ($346 million, +4% cc) a treatment for epilepsy (partial seizures and generalized tonic-clonic seizures) and for several other neuro-psychiatric diseases including bipolar disorders or neuropathic pain, was launched in 1962. It is marketed in approximately 129 countries and, although it faces generic competition in most of them, sales continue to be very stable due to its established position as a gold-standard, first-line treatment. *Tegretol* is also listed as an 'essential medicine' by the World Health Organization.

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Zortress/Certican ($327 million, +36% cc), a transplantation medicine available in more than 90 countries to prevent organ rejection in adult heart and kidney transplant patients, continued to show strong growth in 2014. It is also approved in over 70 countries for liver transplant patients, including the US and EU countries. Everolimus, the active ingredient in *Zortress*/*Certican*, is marketed for other indications under the trade names *Afinitor*/*Votubia*. Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Other Products of Significance

HRT Range ($297 million, 8% cc), encompasses *Vivelle-Dot*/*Estradot*, *Estalis*/*CombiPatch*, *Sequidot* and *Estracomb* MX. *Vivelle-Dot/Estradot*, which makes up the bulk of the HRT Range sales, is a transdermal patch formulation of estradiol hemihydrate. This estrogen replacement therapy is used for the treatment of the symptoms of natural or surgically induced menopause and the prevention of postmenopausal osteoporosis. First launched in May 1999, *Vivelle-Dot/Estradot* is marketed in approximately 29 countries. This product is subject to generic competition outside the US.

Jakavi ($279 million, +72% cc), is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. It is the first JAK inhibitor indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thromboycythemia myelofibrosis. *Jakavi* is currently approved in more than 65 countries worldwide. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US.

Zometa ($264 million, 55% cc), which is used in an oncology setting to reduce or delay skeletal-related events in patients with bone metastases from solid tumors and multiple myeloma, continued to decline as anticipated in 2014 due to generic competition following patent expirations in 2013 on its active ingredient, zoledronic acid.

Trileptal ($265 million, +6% cc), a treatment for epilepsy partial seizures (and generalized tonic-clonic seizures in some countries) was launched in 1973. It is marketed in approximately 97 countries and, although it faces generic competition in most of them, sales are stable due to the continued sales growth outside the EU offsetting the price pressure from generics.

Alcon

Alcon net sales in 2014 grew 3% (+6% in constant currencies, or cc) to $10.8 billion. Growth was driven by key product launches, such as *Centurion* and *LenSx* for cataract surgery, *Azarga* and *Simbrinza* for the treatment of glaucoma, *Ilevro* to treat ocular inflammation, as well as *AirOptix* Colors and the continued rollout of *Dailies Total1* contact lenses.

Regionally, sales were driven by strong performance in emerging growth markets, led by Asia (+13% cc), particularly in China (+23% cc) and Russia (+27% cc).

Latin America delivered robust growth (+17% cc), driven by the Surgical and Ophthalmic Pharmaceuticals franchises.

North America (+4% cc) accelerated its growth in the Surgical franchise, offset by softness in the Ophthalmic Pharmaceuticals franchise. Sales in Europe, the Middle East and Africa (+3% cc) were driven by moderate performance in the Surgical and Ophthalmic Pharmaceuticals franchises. Japan sales

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(+3% cc) grew moderately in the Surgical franchise, offsetting weaker growth in Ophthalmic Pharmaceuticals and Vision Care.

	Year ended Dec 31, 2014 $ m	Year ended Dec 31, 2013 $ m	Change in $ %	Constant currencies change %
Surgical				
Cataract products	3,174	3,037	5	7
of which IOLs	*1,264*	*1,297*	*(3)*	*0*
Vitreoretinal products	615	592	4	7
Refractive/other	284	268	6	8
Total	**4,073**	**3,897**	**5**	**7**
Ophthalmic Pharmaceuticals				
Glaucoma	1,319	1,265	4	7
Allergy/otic/nasal	887	939	(6)	(4)
Infection/inflammation	1,066	1,019	5	7
Dry eye	608	558	9	12
Other	331	327	1	6
Total	**4,211**	**4,108**	**3**	**5**
Vision Care				
Contact lenses	1,897	1,793	6	7
Contact lens care	646	698	(7)	(5)
Total	**2,543**	**2,491**	**2**	**4**
Total net sales	**10,827**	**10,496**	**3**	**6**

Surgical

Surgical franchise sales rose 5% (+7% cc) to $4.1 billion. The increase was driven by strong equipment sales, led by the *Centurion* Vision System for phacoemulsification cataract surgery, the continued growth of the *LenSx* femtosecond laser for refractive cataract surgery, strong sales of vitreoretinal and cataract disposable surgical equipment, as well as the launch of the *Verion* image-guided system.

Alcon experienced a more modest increase in intraocular lens (IOL) sales, driven by strong competition in the US, Japan and EU.

Ophthalmic Pharmaceuticals

Ophthalmic Pharmaceuticals sales grew 3% (+5% cc) to $4.2 billion despite a weak allergy season in the US. Sales were led by glaucoma products such as *DuoTrav*, *Azarga* and the newly-launched *Simbrinza*. *Systane* eye drops to treat the symptoms of dry eye saw double-digit growth.

Within the Infection/Inflammation segment, sales growth (+7% cc) was driven by *Ilevro* and *Durezol*. *Jetrea*, a first-in-class treatment for symptomatic vitreomacular adhesion/traction, continued to gain regulatory approvals, notably in Latin America and Asia.

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Vision Care

Vision Care sales increased 2% (+4% cc) to $2.5 billion. Contact lens sales rose 6% (+7% cc), driven by key launches of *AirOptix* Colors, *Dailies AquaComfort Plus* (*DACP*) Toric, and *DACP* Multifocal, as well as the continued rollout of *Dailies Total1* worldwide.

At the same time, contact lens care solutions declined (7% cc), driven by market shifts to daily disposable lenses, as well as competitive pressure in the US.

Sandoz

Sandoz had net sales of $9.6 billion in 2014, up 4% (+7% in constant currencies, or cc) from the prior year, driven by a 15 percentage points increase in volume, more than offsetting 8 percentage points of price erosion. Performance was driven by strong retail generics and biosimilars sales growth in Asia (excluding Japan) (+15% cc), the US (+14% cc), and Latin America (+10% cc). Sales growth in Western Europe (excluding Germany) was solid at 4% (cc).

Sandoz continued to strengthen its global leadership position in differentiated generics, including medicines that are difficult to develop and manufacture. Differentiated generics accounted for 45% of Sandoz sales.

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Constant currency change
	$ m	$ m	%	%
Retail Generics	7,933	7,663	4	6
Biopharmaceuticals & Oncology Injectables	1,094	888	23	25
Anti-Infectives	535	608	(12)	(12)
Total	**9,562**	**9,159**	**4**	**7**

Retail Generics

In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals. It includes the specialty areas of Dermatology, Respiratory and Ophthalmics. Retail Generics sales worldwide rose 4% (+6% cc) to $7.9 billion. US sales grew 10% (cc), dampened by customer consolidation. Sales in Western Europe (excluding Germany) rose 3% (cc), driven by strong growth in Italy, Nordics and the United Kingdom. German sales were down 1% (cc) due to weak market demand. Emerging growth markets grew strongly, driven by Asia (excluding Japan), up 14% (cc); Central and Eastern Europe, up 4% (cc); and Latin America, up 8% (cc).

Biopharmaceuticals & Oncology Injectables

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- and other biotechnology-based products, which are known as biosimilars, or follow-on biologics. Sandoz also provides biotechnology manufacturing services to other companies. Sales of Biopharmaceuticals & Oncology Injectables rose 23% (+25% cc) to $1.1 billion. In 2014, Sandoz continued to strengthen its global leadership position in biosimilars. In May, Sandoz was the first to apply for approval of a biosimilar in the US under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009, with filgrastim, which is used to decrease the incidence of infection among cancer patients receiving chemotherapy. In January 2015, a US Food and Drug Administration advisory body recommended approval. Sandoz leads the industry with six biosimilars in Phase III clinical trials or registration.

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Three Sandoz biosimilar products occupy the number one position in market share in their respective categories *Omnitrope*, a human growth hormone; *Binocrit* for anemia; and filgrastim under the brand name *Zarzio*. Biosimilars sales in 2014 amounted to $514 million, up 23% (cc) from the previous year, mainly due to continued strong growth across all our brands and regions.

Sandoz also develops, manufactures and markets cytotoxic products for traditional cancer chemotherapy. The Oncology Injectables business now includes a portfolio of more than 25 products. Oncology Injectables sales in 2014 amounted to $477 million, up 29% (cc) from the previous year, mainly due to recent launches in the US.

Anti-Infectives

In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for sale under the Sandoz name and by third-party customers. Anti-Infectives sales in 2014 amounted to $535 million, down 12% (cc) from the previous year, as production capacities were temporarily constrained due to quality upgrades.

Discontinuing Operations

Vaccines

Vaccines net sales amounted to $1.5 billion in 2014, down 23% (21% in constant currencies, or cc) from $2.0 billion in 2013. However, 2013 included the net sales of the divested blood transfusion diagnostics unit. Excluding the diagnostics unit, Vaccines net sales increased 8% (+10% cc) from $1.4 billion a year ago. Demand was solid across the product portfolio, particularly in the Meningitis franchise, with the recent launch of *Bexsero*.

Influenza

Influenza vaccines sales were $476 million, down 10% (8% cc). Novartis was the first to market with vaccines for the 2014 2015 influenza season and shipped 43 million doses of *Flucelvax* and *Fluvirin* in the US.

Meningitis

Meningitis vaccine sales increased 37% to $454 million (+41% cc), benefiting from the strong performance of *Menveo*, *Menjugate* and *Bexsero*. *Bexsero* was awarded breakthrough therapy designation by the US Food and Drug Administration in April 2014, and was approved by the FDA in January 2015. In the United Kingdom, an advisory body recommended including *Bexsero* in the national immunization schedule.

Travel and Pediatrics

Sales of travel and pediatric vaccines grew 9% (+11% cc) to $607 million, driven by tick-borne encephalitis and *Ixiaro* vaccine sales.

Consumer Health

Consumer Health saw sales increase 5% (+8% in constant currencies, or cc) to $4.3 billion in 2014.

Within OTC, *Voltaren*, the seventh-largest global OTC brand, was a key growth driver. Animal Health performance benefited from the 2013 North American re-launch of *Sentinel*, a product for prevention and control of parasites in dogs.

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OTC

OTC sales reached $3.1 billion, up 9% (cc) over the previous year, driven by strong growth of all strategic brands, including *Voltaren* (+22% cc). North America achieved double-digit growth, due largely to increased sales of *Voltaren* in Canada and the US re-launch of *Theraflu* shipments in July. Emerging growth markets also performed strongly with double-digit growth (cc) led by China and Brazil, and with robust growth in Russia.

Animal Health

Animal Health achieved sales of $1.2 billion (+5% cc), boosted by the 2013 North American re-launch of *Sentinel*. Excluding *Sentinel*, Animal Health sales advanced in key markets. Sales of *Deramaxx* and *Onsior*, both non-steroidal anti-inflammatory drugs, continued to grow strongly.

Group operating income

Group operating income amounted to $10.7 billion (2%, +5% cc). Operating income margin was 18.5% of net sales. Group net income rose 11% (+17% cc) to $10.3 billion. Earnings per share (EPS) rose 12% (+18% cc) to $4.21. Free cash flow in 2014 increased by 8% to $10.8 billion, mainly due to higher cash flows from operating activities.

On a more comparable basis, excluding the 2013 results of the blood transfusion diagnostics unit, divested on January 9, 2014, Group operating income increased 1% (+7% cc) to $10.7 billion. Group operating income included a $0.9 billion exceptional gain from the divestment of the blood transfusion diagnostics unit to Grifols S.A. and a $0.3 billion commercial settlement gain which was offset by an exceptional impairment charge of $1.1 billion related to the pending divestment to CSL of the influenza vaccines business. The negative currency impact of 6 percentage points was mainly due to the weakening of emerging market currencies (especially the ruble) and the yen against the US dollar. Operating income margin was 18.5% of net sales, which was 0.1 percentage points less than the prior year. A 0.8 percentage point increase (in constant currencies) from the prior year, was offset by a negative currency impact of 0.9 percentage points. IFRS requires that depreciation and amortization charges on tangible and intangible assets related to the discontinuing operations of the OTC, Animal Health and Vaccines divisions cease from the April 2014 portfolio transformation announcement date. This had a positive impact of $277 million for the year, improving operating income margin by 0.5 percentage points (cc).

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Core key figures[1]

	Year ended Dec 31, 2014	excluding Diagnostics Year ended Dec 31, 2013[2]	Change in $ (excluding Diagnostics)[2]	Change in constant currencies (excluding Diagnostics)[2]
	$ m	$ m	%	%
Core gross profit	**42,093**	**41,763**	**1**	**3**
Marketing & Sales	(14,167)	(14,477)	2	0
Research & Development	(9,572)	(9,613)	0	0
General & Administration	(2,983)	(3,014)	1	0
Other income	586	799	(27)	(27)
Other expense	(1,341)	(1,267)	(6)	(5)
Core operating income	**14,616**	**14,191**	**3**	**8**
Core return on net sales (%)	25.2	24.7		
Core net income	**12,755**	**12,351**	**3**	**8**
Core basic earnings per share ($)	**5.23**	**5.01**	**4**	**10**

(1) For an explanation of non-IFRS measures and reconciliation tables, see " Non-IFRS Measures as defined by Novartis".

(2) 2013 excludes core operating income of $294 million and core net income of $182 million of the blood transfusion diagnostics unit divested on January 9, 2014.

The adjustments made to Group operating income to arrive at core operating income amounted to $3.9 billion (2013: $3.5 billion). These adjustments include amortization of intangible assets of $2.8 billion; the exceptional non-tax deductible US Healthcare Fee levy of $204 million in the year due to a change in regulations; impairment charges of $1.6 billion including an exceptional impairment charge of $1.1 billion; related to the pending divestment to CSL of the influenza vaccines business; and net restructuring charges of $0.7 billion. These were partly offset by the $0.9 billion pre-tax gain from the divestment of the blood transfusion diagnostics unit; a $302 million commercial settlement gain; and a $248 million gain from selling a Novartis Venture Fund investment.

Excluding these items, Group core operating income increased 3% (+8% cc) to $14.6 billion. Core operating income margin in constant currencies increased 1.2 percentage points; currency had a negative impact of 0.7 percentage points, resulting in a net increase of 0.5 percentage points to 25.2% of net sales. The cessation of depreciation charges related to the discontinuing operations had a positive impact of $134 million, improving the core operating income margin by 0.2 percentage points. Additional comments on the changes in the core operating income by division, see " Non IFRS Measures as Defined by Novartis".

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Operating Income by Segment

The following table provides an overview of operating income by segment:

	Year ended Dec 31, 2014	% of net sales	Year ended Dec 31, 2013	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Pharmaceuticals	**8,471**	**26.6**	**9,376**	**29.1**	**(10)**	**(5)**
Alcon	**1,597**	**14.8**	**1,232**	**11.7**	**30**	**43**
Sandoz	**1,088**	**11.4**	**1,028**	**11.2**	**6**	**14**
Corporate continuing operations	(67)		(653)		nm	nm
Continuing operations	**11,089**	**21.3**	**10,983**	**21.2**	**1**	**7**
Discontinuing operations[1]	(353)	(6.1)	(73)	(1.2)	nm	nm
Group operating income	**10,736**	**18.5**	**10,910**	**18.8**	**(2)**	**5**

nm = not meaningful

(1) Discontinuing operations are explained in more detail, see " Factors affecting comparability of year-on-year results of operations" and "Item 18. Financial Statements Notes 3 and 30".

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The following table provides an overview of core operating income by segment:

	Year ended Dec 31, 2014	% of net sales	Year ended Dec 31, 2013	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Pharmaceuticals	**9,514**	**29.9**	**9,523**	**29.6**	**0**	**4**
Alcon	**3,811**	**35.2**	**3,694**	**35.2**	**3**	**8**
Sandoz	**1,571**	**16.4**	**1,541**	**16.8**	**2**	**7**
Corporate continuing operations	(423)		(551)		23	25
Continuing operations	**14,473**	**27.7**	**14,207**	**27.4**	**2**	**7**
Discontinuing operations[1]	143	2.5	(16)	(0.3)	nm	nm
Group core operating income[1]	**14,616**	**25.2**	**14,191**	**24.7**	**3**	**8**

nm = not meaningful

(1) 2013 excludes core operating income of $294 million and core net income of $182 million of the blood transfusion diagnostics unit divested on January 9, 2014.

Continuing Operations

Total operating income from continuing operations of $11.1 billion in 2014 increased 1% (+7% cc) compared to $11.0 billion in the prior year.

Total core operating income from continuing operations of $14.5 billion in 2014 increased 2% (+7% cc) compared to $14.2 billion in the prior year.

Pharmaceuticals

Operating income was $8.5 billion (10%, 5% cc), with the decline mainly due to restructuring and other exceptional charges.

Core operating income, which excludes certain exceptional items, was $9.5 billion (0%, +4% cc). Core operating income margin improved by 0.3 percentage points to 29.9% of net sales, despite the negative effect of 0.8 percentage points of changing currency exchange rates.

Research and development

Research and development for the whole of Novartis totaled $9.9 billion and increased 1% compared to the prior year. As shown in the table, in the Pharmaceuticals Division, Research and Exploratory Development expenditure amounted to $2.7 billion in 2014, up by 2% from 2013, and Confirmatory

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Development expenditures amounted to $4.6 billion, practically unchanged from 2013. As shown in the following table:

	Year ended Dec 31, 2014		Year ended Dec 31, 2013	
		Core R&D[1]		Core R&D[1]
	$ m	$ m	$ m	$ m
Research and Exploratory Development	2,724	2,654	2,664	2,611
Confirmatory Development	4,607	4,343	4,578	4,550
Total	**7,331**	**6,997**	**7,242**	**7,161**
% of Pharmaceuticals net sales	23.1%	22.0%	22.5%	22.2%

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

Alcon

Operating income increased 30% (+43% cc) to $1.6 billion, driven by operational performance, as well as the ending in 2013 of charges related to the acquisition of Alcon.

Core operating income, which excludes certain items, rose +3% (+8% cc) to $3.8 billion. Core operating income margin increased 0.6 percentage points in constant currencies, however that was fully offset by a 0.6 percentage point negative currency effect, resulting in a stable core margin of 35.2% of sales.

Sandoz

Operating income increased 6% (+14% cc) to $1.1 billion. Core operating income, which excludes certain exceptional items, was $1.6 billion (+2%, +7% cc), impacted by high price erosion. Core operating income margin decreased by 0.4 percentage points to 16.4% of net sales, mainly due to a negative impact of 0.5 percentage points due to changing currency exchange rates.

Corporate Income and Expense, Net

Corporate income and expense of continuing operations amounted to a net expense of $67 million in 2014 compared to $653 million in the prior year, mainly due to a $456 million increase in other revenues principally related to the retained Vaccines intellectual property rights, including a $302 million commercial settlement gain and a $248 million gain from the sale of a Novartis Venture Fund investment.

Discontinuing Operations

Total operating loss from discontinuing operations amounted to $353 million in 2014 compared to a loss of $73 million in the prior year.

Total core operating income from discontinuing operations amounted to $143 million in 2014 compared to a loss of $16 million in the prior year.

Vaccines

Operating loss was $552 million in 2014, compared to a loss of $238 million a year earlier, driven by a $1.1 billion impairment charge for the influenza vaccines business, which was mostly offset by the $876 million exceptional gain from the divestment of the blood transfusion diagnostics unit.

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Core operating loss, which excludes certain exceptional items, was $290 million, compared to a loss of $302 million in 2013.

Consumer Health

Operating income reached $470 million compared to $178 million in the prior year, driven by higher gross margin from incremental sales and lower remediation and restructuring expenses for the manufacturing plant in Lincoln, Nebraska, US.

Core operating income increased 52% (+72% cc) to $452 million. Core operating income margin increased by 3.3 percentage points to 10.6% of net sales.

Group Income and Expense, Net

Total expenses recognized in Corporate discontinuing operations in 2014 amounted to $271 million related to certain portfolio transformation transaction and other related expenses compared to a expense of $13 million in 2013.

Non-operating Income & Expense

The following table provides an overview of non-operating income and expense:

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Group operating income	**10,736**	**10,910**	**(2)**	**5**
Income from associated companies	1,920	600	220	220
Interest expense	(704)	(683)	(3)	(6)
Other financial income and expense	(31)	(92)	66	31
Income before taxes	**11,921**	**10,735**	**11**	**17**
Taxes	(1,641)	(1,443)	(14)	(20)
Group net income	**10,280**	**9,292**	**11**	**17**
Attributable to:				
Shareholders of Novartis AG	*10,210*	*9,175*	*11*	*18*
Non-controlling interests	*70*	*117*	*(40)*	*(41)*
Basic EPS ($)	**4.21**	**3.76**	**12**	**18**

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The following table provides an overview of core non-operating income and expense:

	Year ended Dec 31, 2014	Year ended Dec 31, 2013[1]	Change in $	Change in constant currencies
	$ m	$ m	%	%
Group core operating income	**14,616**	**14,191**	**3**	**8**
Income from associated companies	945	877	8	8
Interest expense	(704)	(683)	(3)	(6)
Other financial income and expense	(31)	(48)	35	31
Group core income before taxes	**14,826**	**14,337**	**3**	**9**
Taxes	(2,071)	(1,986)	(4)	(10)
Group core net income	**12,755**	**12,351**	**3**	**8**
Attributable to:				
Shareholders of Novartis AG	*12,685*	*12,234*	*4*	*9*
Non-controlling interests	*70*	*117*	*(40)*	*(41)*
Core basic EPS ($)	**5.23**	**5.01**	**4**	**10**

(1) 2013 excludes the blood transfusion diagnostics unit divested on January 9, 2014.

Income from associated companies

Income from associated companies amounted to $1.9 billion in 2014, compared to $600 million in 2013. The increase was mainly due to the gains recognized on the sale of shares of LTS Lohmann Therapie-Systeme AG, Germany, (LTS) and on the sale of the shares of Idenix Pharmaceuticals, Inc., US, (Idenix) which amounted to $421 million and $812 million, respectively. An additional income of $64 million was recorded on investments in associated companies held by the Novartis Venture Funds, which have been accounted at fair value from January 1, 2014 onwards, consistent with other investments held by these Funds, instead of using the equity method of accounting. The contribution from the investment in Roche of $599 million was approximately in line with the prior-year level.

Core income from associated companies increased to $945 million from $877 million in the prior-year period.

Interest Expense and other financial income and expense

Interest expense increased slightly to $704 million from $683 million in the prior year. Other financial income and expense amounted to a net expense of $31 million, compared to $92 million in 2013, mainly as a result of hedging gains.

Taxes

The total Group's tax rate in the full year of 2014 increased to 13.8% from 13.4%, or 12.9% excluding the divested transfusion diagnostics unit, principally due to the impact of taxes on the various exceptional gains and impairments and other exceptional charges which occurred during the year.

The core tax rate increased slightly to 14.0% from 13.9% in 2013.

Net Income

Group net income of $10.3 billion was up 11% (+17%) or 12% (+19% cc), excluding the divested blood transfusion diagnostics unit, growing ahead of operating income mainly due to higher income from

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associated companies, which included a gain of $0.8 billion from the sale of the shares of Idenix to Merck & Co., and a gain of $0.4 billion from the divestment of the shareholding in LTS, partly offset by an increase in tax expense.

EPS

Earnings per share (EPS) was $4.21 per share, up 12% (+18% cc), or on a more comparable basis excluding the 2013 impact of the blood transfusion diagnostics unit up 14% (+20% cc), growing ahead of net income due to lower average outstanding shares and lower minority interests.

Group core net income of $12.8 billion was up 3% (+8% cc), in line with core operating income.

Core EPS was $5.23 (+4%, +10% cc), growing ahead of core net income due to lower average outstanding shares and lower minority interests.

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2013 Compared to 2012

Key figures

	Year ended Dec 31, 2013	Year ended Dec 31, 2012	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales	**57,920**	**56,673**	**2**	**4**
Other revenues	911	888	3	2
Cost of goods sold	(19,608)	(18,756)	(5)	(5)
Gross profit	**39,223**	**38,805**	**1**	**4**
Marketing & Sales	(14,549)	(14,353)	(1)	(3)
Research & Development	(9,852)	(9,332)	(6)	(6)
General & Administration	(3,060)	(2,937)	(4)	(5)
Other income	1,367	1,049	30	30
Other expense	(2,219)	(2,039)	(9)	(9)
Operating income	**10,910**	**11,193**	**(3)**	**5**
Income from associated companies	600	552	9	9
Interest expense	(683)	(724)	6	6
Other financial income and expense	(92)	(96)	4	30
Income before taxes	**10,735**	**10,925**	**(2)**	**6**
Taxes	(1,443)	(1,542)	6	(1)
Net income	**9,292**	**9,383**	**(1)**	**7**
Attributable to:				
Shareholders of Novartis AG	*9,175*	*9,270*	*(1)*	*7*
Non-controlling interests	*117*	*113*	*4*	*4*
Basic earnings per share ($)	**3.76**	**3.83**	**(2)**	**6**
Free cash flow	**9,945**	**11,383**	**(13)**	

Core Key Figures

	Year ended Dec 31, 2013	Year ended Dec 31, 2012	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core gross profit	**42,158**	**41,847**	**1**	**3**
Marketing & Sales	(14,522)	(14,352)	(1)	(3)
Research & Development	(9,642)	(9,116)	(6)	(6)
General & Administration	(3,035)	(2,923)	(4)	(4)
Other income	808	675	20	20
Other expense	(1,282)	(1,289)	1	0