NOVARTIS AG
Form 20-F
January 27, 2016

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As filed with the Securities and Exchange Commission on January 27, 2016

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, 2015

OR

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

OR

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

Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

Lichtstrasse 35
4056 Basel, Switzerland

(Address of principal executive offices)

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

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

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

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:

2,373,894,817 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 the "EC" are to the European Commission; 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 financial or other impact on Novartis or any of our divisions of the strategic actions announced in January 2016 to focus our divisions, integrate certain functions and leverage our scale; or regarding any potential financial or other impact on Novartis as a result of the creation and operation of NBS; or regarding the potential financial or other impact on Novartis of the transactions with GSK, Lilly or CSL; 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.

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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, 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 Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the strategic actions announced in January 2016, the creation and operation of NBS, or the transactions with GSK, Lilly or CSL. Neither can there be any guarantee that Novartis 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;
- the potential that the strategic benefits, synergies or opportunities expected from the strategic actions announced in January 2016, the creation and operation of NBS, or the transactions with GSK, Lilly or CSL 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 safety, quality or manufacturing issues;
- global trends toward health care cost containment, including ongoing pricing pressures, in particular from increased publicity on pharmaceuticals pricing;
- 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 the continued significant increase in value of the US dollar, our reporting currency, against a number of currencies;
- 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, 2015, 2014 and 2013 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,				
	2015	**2014**	**2013**	**2012**	**2011**
	($ millions, except per share information)				
INCOME STATEMENT DATA					
Net sales to third parties from continuing operations	**49,414**	**52,180**	**51,869**	**51,080**	**51,939**
Operating income from continuing operations	**8,977**	**11,089**	**10,983**	**11,507**	**10,293**
Income from associated companies	266	1,918	599	549	526
Interest expense	(655)	(704)	(683)	(724)	(751)
Other financial income and expense	(454)	(31)	(92)	(96)	(2)
Income before taxes from continuing operations	**8,134**	**12,272**	**10,807**	**11,236**	**10,066**
Taxes	(1,106)	(1,545)	(1,498)	(1,706)	(1,381)
Net income from continuing operations	**7,028**	**10,727**	**9,309**	**9,530**	**8,685**
Net income/(loss) from discontinued operations	10,766	(447)	(17)	(147)	387
Group net income	**17,794**	**10,280**	**9,292**	**9,383**	**9,072**
Attributable to:					
Shareholders of Novartis AG	17,783	10,210	9,175	9,270	8,940
Non-controlling interests	11	70	117	113	132
Basic earnings per share ($)					
Continuing operations	2.92	4.39	3.76	3.89	3.59
Discontinued operations	4.48	(0.18)	0.00	(0.06)	0.16
Total	7.40	4.21	3.76	3.83	3.75
Diluted earnings per share ($)					
Continuing operations	2.88	4.31	3.70	3.85	3.54

Discontinued operations	4.41	(0.18)	0.00	(0.06)	0.16
Total	7.29	4.13	3.70	3.79	3.70
Cash dividends[1]	6,643	6,810	6,100	6,030	5,368
Cash dividends per share in CHF[2]	2.70	2.60	2.45	2.30	2.25

(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 2011 through 2014 were approved at the respective AGMs and dividends for 2015 will be proposed to the Annual General Meeting on February 23, 2016 for approval.

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	Year Ended December 31,				
	2015	2014	2013	2012	2011
			($ millions)		
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial instruments	5,447	13,862	9,222	8,119	5,075
Inventories	6,226	6,093	7,267	6,744	5,930
Other current assets	11,172	10,805	13,294	13,141	13,079
Non-current assets	108,711	87,826	95,712	96,187	93,384
Assets related to discontinued operations		6,801	759		
Total assets	**131,556**	**125,387**	**126,254**	**124,191**	**117,468**
Trade accounts payable	5,668	5,419	6,148	5,593	4,989
Other current liabilities	18,040	19,136	20,170	18,458	18,159
Non-current liabilities	30,726	27,570	25,414	30,877	28,331
Liabilities related to discontinued operations		2,418	50		
Total liabilities	**54,434**	**54,543**	**51,782**	**54,928**	**51,479**
Issued share capital and reserves attributable to shareholders of Novartis AG	77,046	70,766	74,343	69,137	65,893
Non-controlling interests	76	78	129	126	96
Total equity	**77,122**	**70,844**	**74,472**	**69,263**	**65,989**
Total liabilities and equity	**131,556**	**125,387**	**126,254**	**124,191**	**117,468**
Net assets	77,122	70,844	74,472	69,263	65,989
Outstanding share capital	890	898	912	909	895
Total outstanding shares (millions)	2,374	2,399	2,426	2,421	2,407

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 ($)
2011	March 2012	2.25	2.48
2012	March 2013	2.30	2.44
2013	March 2014	2.45	2.76
2014	March 2015	2.60	2.67
2015[1]	March 2016	2.70	2.73[2]

(1) Dividend to be proposed by the Board of Directors to the Annual General Meeting on February 23, 2016 and to be distributed February 29, 2016

(2) Translated into US dollars at the Bloomberg Market System December 31, 2015 rate of $1.011 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 20, 2016, as found on Bloomberg Market System, was CHF 1.00 = $0.998.

Year ended December 31, ($ per CHF)	**Period End**	**Average[1]**	**Low[2]**	**High[2]**
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
2015	1.01	1.04	0.97	1.08
Month				
August 2015			1.02	1.07
September 2015			1.02	1.04
October 2015			1.01	1.05
November 2015			0.97	1.01
December 2015			0.97	1.02
January 2016 (through January 20, 2016)			0.99	1.01

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

(2) Represents the lowest, respectively highest, 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 or to maintain an investment 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 certain key products of our Sandoz Division, are generally protected by patent and other intellectual property rights, which are intended to provide us with exclusive rights to market the products. However, those intellectual property rights have varying strengths and durations. Loss of market exclusivity for one or more important products has 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 occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other intellectual property rights. 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, 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 sometimes 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 or other remedies may not be adequate to cover our 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 or other intellectual property protection.

We already face generic competition in Japan and some EU countries for our best-selling product *Gleevec/Glivec* (cancer). In the US, we have resolved patent litigation with certain generic manufacturers. We have licensed one generic manufacturer to market a generic version of *Gleevec* in the US as of February 1, 2016. In the EU, our *Glivec* intellectual property rights also are being challenged by generic manufacturers.

Diovan and *Co-Diovan/Diovan HCT* (high blood pressure), which had long been our best-selling product, has generic competitors for *Diovan* in the US, EU and Japan and for *Co-Diovan/Diovan HCT* in the US and EU. In Japan, Novartis has resolved patent litigation with a generic manufacturer. Patent protection for *Co-Diovan* will expire in Japan in 2016. In addition, valsartan, the active ingredient in *Diovan*, is also used in the single-pill combination therapies *Exforge/Exforge HCT* (high blood pressure), and despite the existence of separate patents covering the product, *Exforge* faces generic competition in the US. Our *Exforge* patents also face challenges in the EU.

Patent protection for octreotide acetate, the active ingredient in *Sandostatin,* has expired. Generic versions of *Sandostatin* SC are available in the US, EU and Japan. A US patent protects *Sandostatin LAR*, the long-acting version of *Sandostatin* which represents a majority of our *Sandostatin* US sales. This patent is expected to expire in 2017. Patents protecting the *Sandostatin LAR* formulation in the EU and Japan have expired. There is currently no generic competition for *Sandostatin LAR* in the US, EU or Japan.

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, Japan and all of Europe. We hold additional patents with respect to *Exelon* Patch, which makes up a substantial portion of our *Exelon* sales, but generic versions of *Exelon* Patch are on the market in the US and most EU countries.

Certain patents and extensions protecting our top-selling products, *Afinitor* and *Gilenya* will begin to expire in 2018 and 2019, and some of the patents protecting these products are being challenged in the US.

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 2016, we expect an impact on our net sales of approximately $3.2 billion as a result of the loss of intellectual property protection for our products, including *Gleevec/Glivec*. Because we typically have substantially reduced marketing and research and development expenses related to products that are in their final year of exclusivity, we expect that this loss of intellectual property protection also will have an impact on our 2016 operating income in an amount corresponding to a significant portion of the products' lost sales. The magnitude of the impact of generic competition 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 such as Google and IBM that are entering the healthcare field. Physicians, patients and third-party payors 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, Gilenya* and *Afinitor* have been launched. Such products, and other competitive products, could significantly affect the revenues from our products and our results of operations.

Similarly, our Alcon Division, a leader in the eye care industry, has recently suffered declining growth rates due in part to increased competition for its products, across all of its business franchises. To counter this, we are taking steps to accelerate growth to improve the division's sales and profits. Our efforts under this plan are expected to take time to succeed. As a result, such competition and other factors can be expected to affect Alcon's business, financial condition or results of operations in the near term. In addition, despite the implementation of the growth acceleration plan, our efforts to improve Alcon's performance may prove insufficient. Should our growth acceleration efforts fail to accomplish its goals, or fail to do so in a timely manner, it could have a material adverse impact on our business, financial condition or results of operations beyond the near term, as well. See also the discussion of Alcon's new product development efforts in " 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, replace lost revenues and income and take advantage of new technologies" below.

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

Our ability to continue to maintain and grow our business, to replace sales lost due to competition, entry of generics or other reasons, and to bring to market products and medical advances that take advantage of new, and potentially disruptive technologies depends in significant part upon the success of our research and development activities in identifying, and successfully and cost-effectively developing

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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 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 revenues and income lost to generic and other competition.

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 limited available intellectual property protections, the longer it takes to develop a product, the less time there will be for us to recoup our research and development costs. New products must undergo intensive preclinical and clinical testing, and 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 that will further delay us and add substantial expense, that we will 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 risks may include failure of the product candidate in preclinical studies, difficulty enrolling patients in clinical trials, clinical trial holds or other delays in completing clinical trials, 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 Alcon Division faces similar challenges in developing new products and bringing them to market. Alcon's Ophthalmic Pharmaceuticals products must be developed and approved in accordance with essentially the same processes as our Pharmaceuticals Division. Alcon's Surgical and Vision Care products face medical device development and approval processes that are often similarly difficult. Alcon is taking steps to accelerate its growth, and this can be expected to be costly and to require extensive efforts over time. There can be no certainty that Alcon will be successful in these efforts, in either the short- or the long-term, and if Alcon is not successful, there could be a material adverse effect on the success of the Alcon Division, and on the Group as a whole. See also the discussion of Alcon in " Our products face important patent expirations and significant competition" above.

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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, despite significant efforts by us and others, to date many countries do not yet have a fully-developed legislative or regulatory pathway which would facilitate the development of biosimilars and permit biosimilars to be sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Further delays in the development and completion of such regulatory pathways, or any significant impediments that may ultimately be built into such pathways, or any other significant difficulties that may arise in the development or marketing of biosimilars or other differentiated products, 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 biopharmaceuticals business in particular, and could have a material adverse effect on the long-term success of the Sandoz Division and the Group as a whole.

Further, in all of our divisions, our research and development activities must be conducted in an ethical and compliant manner. Among other things, we must be concerned with patient safety, Good Clinical Practices requirements, data integrity requirements, the fair treatment of patients in developing countries, and animal welfare requirements. Should we fail to properly manage such issues, we risk injury to third parties, damage to our reputation, negative financial consequences as a result of potential claims for damages, sanctions and fines, and the potential that our investments in research and development activities could have no benefit to the Group.

If we are unable to cost-effectively maintain an adequate flow of successful new products and new indications for existing products sufficient to maintain and grow our business, cover our substantial research and development costs and the decline in sales of older products that become subject to generic or other competition, and take advantage of technological and medical advances, then 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 operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

Our business is 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, governments, 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, and 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. For more information on such price controls see "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls."

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As a result of such measures, we faced downward pricing pressures on our patented and generic drugs in countries around the world in 2015. These pressures ranged from efforts by many governments and proposals by politicians to reduce the amounts we would be paid for our medicines, intense publicity regarding the pricing of pharmaceuticals, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public deemed excessive, and government investigations into pharmaceutical pricing practices.

We expect these challenges to continue and possibly increase in 2016 as political pressures mount, and 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. Such pressures could have a material adverse impact on our business, financial condition or results of operations, as well as on our reputation.

Failure to comply with law, legal proceedings and government investigations 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. Such legal requirements can vary from country to country and new requirements may be 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 actual or alleged failure to comply with law or with heightened public expectations could lead to 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 civil and criminal government investigations, litigations and law enforcement activities 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 across each of our divisions are, or may in the future be subject to various investigations and legal proceedings that arise or may arise from time to time, such as proceedings regarding sales and marketing practices, pricing, corruption, trade regulation and embargo legislation, product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, insider trading, health and safety, environmental, tax, cybersecurity and data privacy, and intellectual property matters, and are increasingly challenging practices previously considered to be legal.

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 involve large cash payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, such proceedings may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the US and other countries, may lead to civil litigation and otherwise subject us to monetary penalties. Further, judgments and settlements sometimes require companies to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for a period of years. Any such resolutions could have a material adverse impact on our business, financial condition or results of operations, as well as on our reputation.

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Our businesses are and have been subject to a number of these types of cases and governmental investigations, including the following:

In 2014, the Tokyo District Public Prosecutor Office indicted our Japanese affiliate, Novartis Pharma K.K. (NPKK), as well as a former NPKK employee on certain charges relating to the alleged manipulation of data in certain clinical trials. The charges against NPKK are subject to a maximum total fine of JPY 4 million. Trial in this matter commenced in December 2015. In addition, in February 2015, the Japanese Ministry of Health, Labor and Welfare (MHLW) issued a business suspension order for failure to report adverse events, which required NPKK to halt manufacturing and sales in Japan for the period from March 5 to 19, 2015. NPKK is implementing a corrective and preventive action plan in response to a business improvement order and instruction issued by the MHLW in the fourth quarter of 2015 regarding additional instances of delayed adverse events reporting.

In 2013 and 2014, the US government and certain states filed civil charges against our US affiliate, Novartis Pharmaceuticals Corporation (NPC) in federal court in the Southern District of New York, asserting federal False Claims Act and state law claims related to alleged unlawful contractual discounts and rebates to specialty pharmacies in connection with certain of our products. The US government alleged substantial damages, including treble damages and civil penalties of up to $11,000 per claim, which according to the government could exceed $2 billion. In the second half of 2015, NPC reached a settlement with all plaintiffs, including the United States Department of Justice, 45 states (made up of the eleven intervening states, as well as all the other states which were either part of the relator's complaint, or which reimbursed prescriptions of *Myfortic* and *Exjade* during the relevant time period), the District of Columbia and the qui tam relator. This resolves all the above-described claims related to *Myfortic*, *Exjade*, *Tasigna*, *Gleevec* and *TOBI.* As part of the settlement, NPC agreed to pay $390 million plus additional legal expenses to plaintiffs, and agreed with the Office of Inspector General of the US Department of Health & Human Services on an amendment and extension of its current Corporate Integrity Agreement until 2020.

A number of significant legal matters remain pending against us. For more detail 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.

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

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

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 standards. In recent years, health authorities have substantially intensified their scrutiny of manufacturers' compliance with such requirements. If we or our third-party suppliers fail to comply fully with these

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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 many of 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. In October 2015, the FDA issued a warning letter to our Sandoz Division concerning their sites in Kalwe and Turbhe, India, relating to documentation practices in Kalwe and sterile manufacturing practices in Turbhe that were identified during an inspection in August 2014. Though we have taken steps to respond to the warning letter, there can be no guarantee that FDA's concerns will be met.

In order to meet increasing health authority expectations and our own high quality standards, we are devoting substantial time and resources to remediate issues, 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 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 that 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, inability to obtain product or raw materials from a sole source of supply, 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, as well as our reputation. 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. In addition, we continue to see weak economic growth or a slowing of economic growth rates in certain emerging growth markets, such as China, Russia, Brazil and India. 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 and Europe, as well as the difficult conditions existing in parts of the Middle East and places such as Ukraine, as well as the ongoing refugee crisis, anti-immigrant activities, social unrest and fears of terrorism that have followed in many countries. 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, financial weakness in certain countries 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 are experiencing high inflation rates and have taken steps to introduce exchange controls and limit companies from distributing retained earnings or paying intercompany payables due from those countries. The most significant country in this respect is Venezuela, where we are exposed to a potential devaluation loss in the income statement on our total intercompany balances with our subsidiaries there, which at December 31, 2015 amounted to $0.3 billion. In November 2015, one of our Venezuelan subsidiaries agreed with Venezuelan authorities to settle a substantial part of our existing intercompany trade payables dated on or before December 31, 2014 in a transaction that, in turn, required us to use a significantly devalued US dollar/Venezuela bolivar exchange rate for consolidation of the financial statements of our Venezuela subsidiaries. The use of the new exchange rate resulted in a $211 million loss from the re-measurement of the intra-Group and third party liabilities. Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future. See also "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources Effects of Currency Fluctuations" and " Condensed Consolidated Balance Sheets," and "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, our business and results of operations including 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

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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 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 medical devices to help cope with rising costs and difficult economic times.

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

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 " Changes in tax laws or their application could adversely affect our results of operation" and " 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.

In 2015, the US dollar continued its significant increase in value against most currencies. In particular, the average value of the euro, the Japanese yen and emerging market currencies (especially the ruble) decreased in 2015 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. In addition, in 2015, China took steps to devalue its currency, and the value of its currency against the US dollar has continued to decline.

There is a risk that other countries could also take steps that could significantly impact the value of their currencies. Such steps could include "quantitative easing" measures and potential withdrawals by countries from common currencies. In addition, certain countries are or may experience periods of high inflation. This could lead these countries to devalue their currencies, and to set exchange controls, as, for example, Venezuela has done. Such steps taken by Venezuela have impacted our financial results. See " 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" above. Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

Despite measures undertaken to reduce, or hedge against, foreign currency exchange risks, because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including

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expenditures in Swiss francs that are significantly higher than our revenues in Swiss francs, such exchange rate volatility may negatively and materially impact the Group's business, results of operations and financial condition, and may impact the reported value of our net sales, earnings, assets and liabilities. In addition, the timing and extent of such volatility can be difficult to predict. Further, depending on the movements of particular foreign exchange rates, the Group may be materially adversely affected at a time when the same currency movements are benefiting some of our competitors.

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, the strategic reorganizations we announced in January 2016, 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 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.

In 2015, we completed a series of transactions intended to transform our portfolio of businesses. In these transactions, we acquired GSK oncology products and certain related assets; created a joint venture with GSK in consumer healthcare of which Novartis owns 36.5%; divested our vaccines business (excluding the influenza vaccines business) to GSK; divested our Animal Health business to Lilly; and divested our influenza vaccines business to CSL. In 2014, we had also divested the blood transfusion diagnostics unit to Grifols S.A. that had been part of our former Vaccines and Diagnostics Division. In agreeing to these transactions, we expect to achieve certain strategic benefits, synergies and opportunities, including certain financial results, but there can be no certainty that such expected benefits will be fully realized or that they will be realized at any particular time.

In addition, as part of our strategy, from time to time we reassess the optimal organization of our business, including the allocation of products by division and the level of centralization and simplification of certain functions across the Group, to better align those products and functions with the capabilities and expertise required for competitive advantage. As an example of this, in January 2016 we announced a series of strategic actions intended to further focus our divisions, including focusing our Alcon Division on its Surgical and Vision Care franchises, strengthening our ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to our Pharmaceuticals Division, and shifting selected

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mature pharmaceutical products from our Pharmaceuticals Division into Sandoz. We also announced steps to increase Group-wide coordination of drug development, and to improve efficiency with an integrated manufacturing operation and more shared commercial and medical services at the country level. We expect these actions to further strengthen our competitive position, enable us to maintain our leading position in research and development, and free resources for our growth priorities. 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 businesses and functions involved will be successfully integrated into the new organizations and that key personnel will be retained. Disruption from the reorganizations may make it more difficult to maintain relationships with customers, employees or suppliers, and may result in the Group not achieving the expected productivity and financial benefits, including potential sales declines and lost profits.

Similarly, in 2014 we created 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. 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, and may result in the Group not achieving the expected productivity and financial benefits.

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 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.

We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, primarily due to acquisitions. As a result, significant impairment charges may result in the future if the expected fair value of the goodwill and other intangible assets would be less than their carrying value on the Group's consolidated balance sheet at any point in time.

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 2015, for example, we recorded intangible asset impairment charges of $347 million. 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, 2015 we had $16.3 billion of non-current financial debt and $5.6 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, if interest rates rise, this amount may increase. In addition, our

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existing debt may limit our ability to engage in transactions or otherwise may place us at a competitive disadvantage relative to competitors that have less debt. We may also 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 and that our reputation may suffer. Any such failures by third parties could have a material adverse effect on our business, financial condition, results of operations or reputation.

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 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 in recent years experienced proportionately higher sales growth and an increasing contribution to the industry's global performance. In 2015, our Continuing Operations generated $12.4 billion, or approximately 25% (2014: 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 $37.0 billion, or approximately 75% (2014: 74%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 7% in constant currencies in 2015, compared to 4% sales growth in constant currencies in the Established Markets during the same period. As a result of this trend, we continue to take steps to increase our activities in the Emerging Growth Markets, and have been making significant investments in our businesses in those countries.

In the past year, however, certain of these Emerging Growth Market countries, including Brazil, India, China and Russia, have experienced economic slowdowns. As a result, there can be no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will once again experience growth rates significantly in excess of the world's largest markets. In particular, 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 may be susceptible to political and social instability. See " 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" above. Many of these countries are subject to increasing political and social pressures, including

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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. See " Our business is increasingly affected by pressures on pricing for our products," and "Our products face important patent expirations and significant competition" above.

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, for example, have been well publicized standards of acceptable behavior may be lower than such standards in Established Markets, or we may be required to rely on third-party agents, in each case putting us at risk of liability and reputational damage. 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 as happened in China and Russia, among others, in the past year and we cannot offset the devaluations with price increases, then our products may become less profitable, or may otherwise impact our reported financial results. Currency devaluation risk may also exist in countries with high inflation economies. Should these countries take steps that cause their currencies to be devalued, we may realize a significant financial loss. See " 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" and " Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," above. Ongoing conditions in such high inflation countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

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 biosimilars and other 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 biosimilars and other differentiated products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz.

In addition, the division faces intense competition from 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.

Sandoz has also invested heavily in the development of biosimilar drugs, despite the fact that regulations concerning their marketing and sale in certain countries, including in the US, are still under development or not entirely clear. If, despite ongoing efforts by us and others to encourage the

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development of such regulations, such regulations do not ultimately favor the development and sale of biosimilar products, then we may fail to achieve expected returns on the investments by Sandoz in the development of biosimilars. 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. While most of our plans are now defined contribution plans, certain of our associates remain under defined benefits plans. For these defined benefits plans, 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 used to determine the 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 or negative 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 and increasing political and social instability 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 that tax profits at more favorable rates. In recent years, tax authorities around the world have increased their scrutiny of company tax structures, and have become more rigid in exercising any discretion they may have. As a result, companies' flexibility to optimally structure their organizations for business and tax purposes may be significantly reduced. In addition, the public is increasingly taking an interest in what the tax burden of multinational companies should be. Any changes in tax laws or in the laws' application that may result from this, 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.

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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 materially affect patient confidence in the authentic product, and harm the business of companies such as ours or lead to litigation. In addition, it is possible that adverse events caused by unsafe counterfeit products could 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 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 14%, 11% and 5%, respectively, of Group net sales in 2015. The largest trade receivables outstanding were for these three customers, amounting to 13%, 9% and 6%, respectively, of the Group's trade receivables at December 31, 2015. 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. In particular, 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.

In addition, 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. Moreover, many members of younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles.

The supply of talent for certain key functional and leadership positions is decreasing, and a talent gap is 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. In addition, the geographic mobility of talent is expected to decrease in the future, with talented individuals in developed and emerging countries anticipating ample career opportunities closer to home than in the past. This decrease in mobility may be worsened by anti-immigrant sentiments in many countries, and laws discouraging immigration.

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,

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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, despite significant efforts on our part, 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.

Significant breaches of data security or disruptions of information technology systems, including by cyber-attack or other security breach, and breaches of the privacy rights of third parties 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. In addition, Novartis and our employees rely on internet and social media tools and mobile technologies as a means of communications, and to gather information. We are also increasingly seeking to develop technology-based products such as mobile applications that go "beyond the pill" to improve patient welfare in a variety of ways, which could result in us gathering information about patients and others electronically.

The size and complexity of our information technology systems, and, in some instances, their age, make them potentially vulnerable to external or internal security breaches, breakdowns, malicious intrusions malware, misplaced or lost data, programming or human errors, or other similar events. Although we have devoted and continue to devote significant resources and management attention to the protection of our data and information technology, like many companies, we have experienced such events and expect to continue to experience them in the future. We believe that the data security breaches we have experienced to date have not resulted in significant disruptions to our operations, and will not have a significant adverse effect on our current or future results of operations. However, we may not be able to prevent breakdowns or breaches in our systems that could have a material adverse effect on our business, financial condition, results of operation or reputation.

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. Such potential information technology issues could lead to the loss of important information such as trade secrets or other intellectual property and could accelerate development or manufacturing of competing products by third parties. In addition, malfunctions in software or devices that make significant use of information technology, including our Alcon surgical equipment, could lead to a risk of harm to patients.

Our use of information technologies, including internet, social media, mobile technologies, and technology-based medical devices, as well as other routine business operations, sometimes involve our gathering personal information (including sensitive personal information) regarding our patients, vendors, customers, employees, collaborators and others. Breaches of our systems or other failures to protect such information could expose the personal information of third parties to unauthorized persons. Any such information or other privacy breaches could give rise to significant potential liability and reputational harm. In addition, we make substantial efforts to ensure that any international transfers of personal data are done in compliance with applicable law. Any restrictions that may be placed on our ability to transfer such data could have a material adverse effect on our business, financial condition, results of operations and reputation.

In addition, to the extent that we seek as a company to use internet, social media and mobile tools as a means to communicate with the public about our products or about the diseases our products are intended to treat, there continue to be significant uncertainties as to the rules that apply to such

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communications, and as to the interpretations that health authorities will apply in this context to the rules that do 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.

Any such breaches of data security or information technology disruptions or privacy violations could give rise to the loss of trade secrets or other intellectual property, to the public exposure of personal information, and to interruptions to our operations, and could result in liability or enforcement actions, which could require us to expend significant resources to continue to modify or enhance our protective measures and to remediate any damage. Such events could have a material adverse effect on our business, financial condition, results of operations and reputation.

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, in some cases over many years. 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 environmental contamination caused by us adversely impact third parties, if we fail to properly manage the safety of our facilities and the environmental risks, or if we are required to further increase our provisions for environmental liabilities in the future, this could have a material adverse effect on our business, financial condition, results of operations, and on our reputation. See also "Item 4.D Property, Plants and Equipment Environmental Matters" and "Item 18. Financial Statements Note 20."

Extreme weather events, 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 or extreme weather risks like hurricanes, tornadoes or floods, or other events that may result from the impact of climate change on the environment. As a result of such events, 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.

In addition, 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. Other major facilities 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

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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 2013-January 2016

2016

January	Novartis announces leadership changes effective February 1, 2016. Mike Ball has been appointed Division Head and CEO Alcon, succeeding Jeff George; Dr. Vas Narasimhan has been appointed Global Head Drug Development and Chief Medical Officer; and André Wyss has been appointed President, Novartis Operations.
	Novartis announces that it is taking a number of steps to further build on its strategy, including focusing the Alcon Division on its Surgical and Vision Care franchises, with specific actions identified to accelerate growth, and strengthening the ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to the Pharmaceuticals Division; centralizing manufacturing operations across divisions within a single technical operations unit; increasing Group-wide coordination of drug development by establishing a single Global Head of Drug Development and centralizing certain common functions such as the Chief Medical Office; and shifting selected mature, non-promoted pharmaceutical products from the Pharmaceuticals Division into the Sandoz Division.
	Novartis announces a collaboration and licensing agreement with Surface Oncology, which gives Novartis access to four pre-clinical programs in immuno-oncology.

2015

November	Novartis completes a $3 billion bond offering under its US SEC Registration Statement on Form F-3.
October	Novartis announces the acquisition of Admune Therapeutics to broaden its portfolio of cancer immunotherapies.

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September	Novartis announces the appointment of Dr. James E. Bradner as President of the Novartis Institutes for BioMedical Research and a member of the Executive Committee of Novartis, to be effective March 1, 2016, concurrent with the retirement of Dr. Mark C. Fishman, who will reach his contractual retirement age in March 2016.
	Novartis announces the launch of Novartis Access, a portfolio of affordable medicines to treat chronic diseases in lower-income countries offered to governments, non-governmental organizations and other public-sector healthcare providers for $1 per treatment, per month.
	Novartis announces that it has entered into a global collaboration with Amgen to commercialize and develop neuroscience treatments.
August	Novartis announces an agreement to acquire all remaining rights to GSK's ofatumumab to develop treatments for multiple sclerosis and other autoimmune indications. This transaction was completed on December 21, 2015.
July	Novartis announces a swap of three mid-stage clinical assets for equity and a share of milestones and royalties on future commercial sales with Mereo BioPharma Group Limited.
June	Novartis announces that it has entered into an agreement to acquire Spinifex Pharmaceuticals, Inc., a US and Australian-based, privately held development stage company focused on developing a peripheral approach to treat neuropathic pain such as EMA401, a novel angiotensin II Type 2 receptor (AT2R) antagonist. This acquisition was completed on July 24, 2015.
March	Novartis announces entry into an alliance with Aduro Biotech focused on discovery and development of next-generation cancer immunotherapies targeting the STING signaling pathway, and the launch of a new immuno-oncology research group.
February	Novartis completes a CHF 1.375 billion bond offering listed on the SIX Swiss Exchange.
2014	
October	Novartis announces a definitive agreement with CSL of Australia to divest its influenza vaccines business for $275 million. This divestment was completed effective July 31, 2015.
	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.
	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.

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May	Novartis enters into a licensing and commercialization agreement with Ophthotech Corporation for the exclusive rights to market *Fovista* (pegpleranib; OAP030, anti-PDGF aptamer) outside the US. In November 2015, Genentech entered into an agreement with Novartis to participate in certain rights related to the Novartis licensing and commercialization agreement with Ophthotech Corporation for OAP030.
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%. These transactions were completed on March 2, 2015.
	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 on January 9, 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.

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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.
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.

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 expenditures in research and development, see the sections headed "Research and Development" included in the descriptions of our Pharmaceuticals Division and Alcon Division, and the section headed "Development and Registration" included in the description of our Sandoz Division under "Item 4.

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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." For more information on the transactions with GSK, Lilly or CSL, 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 products and cost-saving generic pharmaceuticals.

Following the completion of a series of transactions in 2014 and 2015, the Group's portfolio is organized into three global operating divisions. In addition, we separately report the results of Corporate activities. The disclosure in this Item focuses on these continuing operations, which are made up of Pharmaceuticals, Alcon, Sandoz and Corporate activities. In addition, from March 2, 2015, the date of the completion of a series of transactions with GSK, continuing operations also includes the results from the oncology assets acquired from GSK and the 36.5% interest in the GSK consumer healthcare joint venture (the latter reported as an investment in associated companies). We sold our Vaccines Division, excluding our influenza business, to GSK. Our influenza vaccines business was sold to CSL and our Animal Health Division was sold to Lilly. For more detail on these transactions see, "Item 10.C Material Contracts."

Continuing Operations:

Pharmaceuticals: Innovative patent-protected prescription medicines

Alcon: Surgical, ophthalmic pharmaceutical and vision care products

Sandoz: Generic pharmaceuticals and biosimilars

Corporate activities

Discontinued Operations:

Vaccines and Diagnostics: Preventive human vaccines and blood-testing diagnostics

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

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 from Corporate activities 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.

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

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, and is headquartered in Cambridge, Massachusetts. More than 6,000 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, Singapore and China. For more information about NIBR, see " Pharmaceuticals Research and Development Research program," below.

Novartis Business Services (NBS), our shared services organization, consolidates support services across Novartis divisions, helping to drive efficiency, standardization and simplification. NBS includes six service domains: human resources services, real estate and facility management, procurement, information technology, product lifecycle services and financial reporting and accounting operations. NBS has approximately 9,500 associates. Moving from division-specific services to a cross-divisional model, NBS continues to scale up the offshoring of transactional services to its five selected Global Service Centers in Mexico City, Mexico; Kuala Lumpur, Malaysia; Prague, Czech Republic; Hyderabad, India; and Dublin, Ireland.

Our continuing operations achieved net sales of $49.4 billion in 2015, while net income from continuing operations amounted to $7.0 billion. Research & Development expenditure in 2015 amounted to $8.9 billion ($8.7 billion excluding impairment and amortization charges). Of total net sales from continuing operations, $12.4 billion, or 25%, came from Emerging Growth Markets, and $37.0 billion, or 75%, 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 118,700 full-time equivalent associates as of December 31, 2015. Our products are available in approximately 180 countries around the world.

In September 2015, Novartis announced the launch of Novartis Access, a portfolio of 15 medicines to treat chronic diseases in low- and middle-income countries. The portfolio addresses cardiovascular diseases, diabetes, respiratory illnesses, and breast cancer and will be offered to governments, non-governmental organizations (NGOs) and other public-sector healthcare providers for $1 per treatment, per month.

In 2016, having completed our portfolio transformation and operationalized NBS, we are taking further steps to build on our strategy. We are focusing our Alcon Division on its Surgical and Vision Care franchises. Within these franchises, we have identified key actions to accelerate growth in 2016 and beyond. These include optimizing intraocular lens (IOL) innovation and commercial execution; prioritizing and investing in promising pipeline opportunities; ensuring best-in-class service, training and education for eye care professionals; improving sales force effectiveness; and investing in direct to consumer activities for key brands.

We are strengthening our ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to our Pharmaceuticals Division. This is expected to simplify our ophthalmic medicines business, leverage Alcon's strong brand with Pharmaceuticals Division development and marketing capabilities, and help us accelerate innovation and growth in eye care.

At the same time, we are shifting selected mature, non-promoted pharmaceutical products from our Pharmaceuticals Division into Sandoz, which has proven experience in managing mature products successfully.

To increase innovation even further, we are increasing Group-wide coordination of drug development. We are establishing a single Global Head of Drug Development to improve resource allocation and standards across our divisions. We are also centralizing certain common functions, such as the Chief Medical Office, which will cover safety and pharmacovigilance policy for the Group.

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To further improve efficiency, we are centralizing our manufacturing operations across our divisions within a single technical operations unit. The new unit is expected to optimize capacity planning and lower costs through simplification, standardization and external spend optimization. Centralization is also expected to improve our ability to develop next-generation technologies, implement continuous manufacturing and share best practices across divisions.

We expect these changes to generate over $1.0 billion in annual cost savings from 2020, with the ramp-up starting in 2016. Associated with these changes we expect one-time restructuring costs of approximately $1.4 billion spread over five years. We plan to use the net savings to fund innovation and improve our profit margins.

In addition, we announced leadership changes effective February 1, 2016. Mike Ball has been appointed Division Head and CEO Alcon, and will be a member of the Executive Committee of Novartis (ECN). Mr. Ball joins Novartis from Hospira, where he was CEO from 2011 until recently. Mr. Ball succeeds Jeff George, who has decided to leave Novartis. Dr. Vas Narasimhan has been appointed Global Head Drug Development and Chief Medical Officer, a new position in the ECN. André Wyss, already a member of the ECN, Head NBS and Country President for Switzerland, has been appointed President, Novartis Operations. In his new role, he will assume responsibility for the integrated Technical Operations organization as well as for Global Public & Government Affairs, in addition to his current responsibilities.

Except as described above and as briefly described in " Alcon" below, and "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Results of Operations Alcon," this Form 20-F reflects the organization of the Group prior to the changes described above.

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. Our Pharmaceuticals Division also includes a franchise focused on the development and commercialization of Cell and Gene Therapies.

On March 2, 2015, we completed the acquisition of the oncology products of GSK, together with certain related assets. In addition, we acquired 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.

In 2015, the Pharmaceuticals Division accounted for $30.4 billion, or 62%, of Group net sales, and for $7.6 billion, or 81%, 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

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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-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 2015, Alcon accounted for $9.8 billion, or 20%, of Group net sales, and for $0.8 billion, or 9%, 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 intermediary products including active pharmaceutical ingredients. 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 areas of cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies. Finished dosage form anti-infectives sold to third parties are also part of Retail Generics. 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 and provides biotechnology manufacturing services to other companies, and in Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

In 2015, Sandoz accounted for $9.2 billion, or 18%, of Group net sales, and for $1.0 billion, or 11%, of Group operating income (excluding Corporate income and expense, net).

Discontinued Operations:

Vaccines and Diagnostics Division

Prior to the completion of certain transactions in 2014 and 2015, our Vaccines and Diagnostics Division researched, developed, manufactured, distributed and sold human vaccines and blood-testing products worldwide. On January 9, 2014, we completed the divestment of our blood transfusion diagnostics unit to Grifols S.A. On March 2, 2015, we completed the divestment of our Vaccines Division (excluding its influenza vaccines business) to GSK. On July 31, 2015, we completed the divestment of our influenza vaccines business to CSL Limited.

Consumer Health

Prior to the completion of certain transactions in 2015, Consumer Health consisted of our OTC (Over-the-Counter) and Animal Health Divisions. On January 1, 2015 we completed the divestment of our Animal Health Division to Lilly. On March 2, 2015, we completed the divestment of our OTC Division, which we contributed to a new consumer healthcare joint venture with GSK, of which we own 36.5%.

PHARMACEUTICALS

Overview

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

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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. Our Pharmaceuticals Division also includes a franchise focused on the development and commercialization of Cell and Gene Therapies.

On March 2, 2015, we completed the acquisition of the oncology products of GSK, together with certain related assets. In addition, we acquired 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.

The Pharmaceuticals Division is the largest contributor among the divisions of Novartis and reported consolidated net sales of $30.4 billion in 2015, which represented 62% of the Group's net sales.

The product portfolio of the Pharmaceuticals Division includes more than 60 key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 135 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. 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. Please see " Intellectual Property" for general information on intellectual property and regulatory data protection, and for further information on the status of patents and exclusivity for Pharmaceuticals Division products.

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Selected Marketed Products

Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
Oncology	*Afinitor/Votubia* and *Afinitor Disperz/Votubia* dispersible tablets	everolimus	Advanced renal cell carcinoma after failure of treatment with VEGF-targeted therapy	Tablet Dispersible tablets for oral suspension
			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	
	Arzerra	ofatumumab	In combination with chlorambucil for first- line chronic lymphocytic leukemia (CLL)	Intravenous infusion
			In combination with chlorambucil or bendamustine for first-line CLL	
			CLL refractory to fludarabine and alemtuzumab	
			Extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL	
	Atriance/Arranon	nelarabine	Relapsed and/or refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma	Solution for infusion
	Exjade and *Jadenu*	deferasirox	Chronic iron overload due to blood transfusions and non-transfusion dependent thalassemia	Dispersible tablet for oral suspension Oral film-coated tablet
	Farydak	panobinostat	Relapsed and/or refractory multiple myeloma, in combination with bortezomib and dexamethasone, after at least two prior regimens including bortezomib and an immunomodulatory agent	Capsules
	Femara	letrozole	Hormone receptor-positive early breast cancer in postmenopausal women following surgery (upfront adjuvant therapy)	Tablet
			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)	
Gleevec/Glivec	imatinib mesylate/imatinib	Certain forms of Ph+ chronic myeloid leukemia	Tablet Capsules
		Certain forms of KIT+ gastrointestinal stromal tumors	
		Certain forms of acute lymphoblastic leukemia Dermatofibrosarcoma protuberans	
		Hypereosinophilic syndrome	
		Aggressive systemic mastocytosis	
		Myelodysplastic/myeloproliferative diseases	

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Hycamtin	topotecan	Relapsed small cell lung cancer	Capsule Powder for infusion
			Metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy	
			Small cell lung cancer sensitive disease after failure of first-line chemotherapy	
			Combination therapy with cisplatin for Stage IV-B, recurrent, or persistent carcinoma of the cervix which is not amenable to curative treatment with surgery and/or radiation therapy	
	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
			Polycythemia vera in adult patients who are resistant to or intolerant of hydroxyurea	
	Odomzo	sonidegib	Locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or is not a candidate for surgery or radiation therapy	Capsule
	Proleukin	aldesleukin	Metastatic renal cell carcinoma	Powder for injection or infusion
			Metastatic melanoma	
	Promacta/Revolade	eltrombopag	Thrombocytopenia in adult and pediatric patients one year and older with chronic immune (idiopathic) thrombocytopenia who have had insufficient response to corticosteroids, immunoglobulins, or splenectomy	Tablet Eltrombopag for oral suspension
			Thrombocytopenia in patients with chronic hepatitis C to allow initiation and	

		maintenance of interferon-based therapy	
		Severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy	
Sandostatin LAR and *Sandostatin* SC	octreotide acetate	Acromegaly	Vial Ampoule/pre-filled syringe
		Symptom control for certain forms of neuroendocrine tumors	
		Delay of tumor progression in patients with midgut tumors	
Signifor and *Signifor* LAR	pasireotide	Cushing's disease	Solution for subcutaneous injection in ampoule
		Acromegaly	Powder and solvent for suspension for IM injection
Tafinlar + *Mekinist*	dabrafenib + trametinib	BRAF V600+ metastatic melanoma	Capsule (*Tafinlar*) Tablet (*Mekinist*)
Tasigna	nilotinib	Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec*	Capsule
		First-line chronic myeloid leukemia	

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Tykerb	lapatinib	In combination with capacitabine for the treatment of patients with HER2+ advanced or metastatic breast cancer who have progressed on prior trastuzumab therapy	Tablet
			In combination with trastuzumab for patients with HR-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) plus chemotherapy	
			In combination with paclitaxel for first line treatment of patients with HER2+ metastatic breast cancer for whom trastuzumab is not appropriate	
			In combination with an aromatase inhibitor for the treatment of patients with hormone sensitive metastatic breast cancer	
	Votrient	pazopanib	Advanced renal cell carcinoma	Tablet
			Certain types of advanced soft tissue sarcoma after prior chemotherapy	
	Zofran	ondansetron	Use in children and adults for the prevention of chemotherapy induced nausea and vomiting and prevention of post-operative nausea and vomiting, and in adults for the prevention of radiation-induced nausea and vomiting	Tablet Oral solution Orally disintegrating tablets Solution for injection/infusion
	Zometa	zoledronic acid	Skeletal-related events from bone metastases (cancer that has spread to the bones)	Vial/4mg Ready-to-use
			Hypercalcemia of malignancy	
	Zykadia	ceritinib	Anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer	Capsules
Cardio-Metabolic	*Entresto*	sacubitril/valsartan	Chronic heart failure with reduced ejection fraction	Tablet
	Galvus and *Eucreas*	*Galvus*: vildagliptin *Eucreas*: vildagliptin and metformin	Type 2 diabetes	Tablet

Immunology and Dermatology	*Cosentyx*	secukinumab	Active ankylosing spondylitis in adults who have responded inadequately to conventional therapy	Lyophilized pre-filled syringe; Auto-injector
			Active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate	
			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)	
	Ilaris	canakinumab	Cryopyrin-associated periodic syndromes	Lyophilized powder for reconstitution for subcutaneous injection
			Systemic juvenile idiopathic arthritis	
			Gouty arthritis	
	Myfortic	mycophenolic acid (as mycophenolate sodium)	Prophylaxis of organ rejection in patients receiving allogeneic renal transplants	Gastro-resistant tablet

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Neoral and *Sandimmune*	cyclosporine, USP Modified	Prevention of rejection following certain organ transplantation	Capsule Oral solution Intravenous (*Sandimmune*)
			Non-transplantation autoimmune conditions such as severe psoriasis and severe rheumatoid arthritis	
	Simulect	basiliximab	Prevention of acute organ rejection in de novo renal transplantation	Vial for injection or infusion
	Xolair	omalizumab	Chronic spontaneous urticaria/	Lyophilized powder in vial and liquid formulation in pre-filled syringes
			Chronic idiopathic urticaria	
			See also, "Respiratory"	
	Zortress/Certican	everolimus	Prevention of organ rejection (heart, liver and kidney)	Tablet Dispersible tablet
Retina	*Lucentis*	ranibizumab	Neovascular age-related macular degeneration	Intravitreal injection
			Visual impairment due to diabetic macular edema Visual impairment due to macular edema secondary to central retinal vein occlusion	
			Visual impairment due to macular edema secondary to branch retinal vein occlusion	
			Visual impairment due to choroidal neovascularization secondary to pathologic myopia	
Respiratory	*Arcapta Neohaler/ Onbrez Breezhaler*	indacaterol	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Seebri Neohaler/ Seebri Breezhaler	glycopyrronium bromide (glycopyrrolate)	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	TOBI and *TOBI Podhaler*	tobramycin	Pseudomonas aeruginosa infection in cystic fibrosis	Nebulizer solution (*TOBI)*, Inhalation powder (*TOBI Podhaler*)
	Utibron Neohaler/ Ultibro Breezhaler	indacaterol / glycopyrronium bromide (glycopyrrolate)	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Xolair	omalizumab	Severe allergic asthma	Lyophilized powder in vial and liquid formulation in pre-filled syringes

			See also, "Immunology and Dermatology"	
Neuroscience	*Comtan*	entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet
	Exelon	rivastigmine	Mild-to-moderate Alzheimer's disease dementia	Capsule Oral solution Transdermal patch
			Severe Alzheimer's disease dementia Dementia associated with Parkinson's disease	
	Extavia	interferon beta-1b	Relapsing remitting and/or relapsing forms of multiple sclerosis in adult patients	Subcutaneous injection
	Gilenya	fingolimod	Relapsing forms of multiple sclerosis	Capsule

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet
Established Medicines	*Cibacen*	benazepril hydrochloride	Hypertension	Tablet
			Adjunct therapy in congestive heart failure	
			Progressive chronic renal insufficiency	
	Clozaril/Leponex	clozapine	Treatment-resistant schizophrenia	Tablet
			Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and psychotic disorders	
	Coartem/Riamet	artemether and lumefantrine	Plasmodium falciparum malaria or mixed infections that include Plasmodium falciparum	Tablet Dispersible tablet for oral suspension
			Standby emergency malaria treatment	
	Diovan	valsartan	Hypertension	Tablets Capsules Oral solution
			Heart failure	
			Post-myocardial infarction	
	Diovan HCT and *Co-Diovan*	valsartan and hydrochlorothiazide	Hypertension	Tablet
	Exforge and *Exforge HCT*	valsartan and amlodipine besylate	Hypertension	Tablet
	Focalin and *Focalin XR*	dexmethylphenidate HCl and dexmethylphenidate extended release	Attention deficit hyperactivity disorder	Tablet Capsule
	Foradil	formoterol	Asthma	*Aerolizer* (capsules) Aerosol
			Chronic obstructive pulmonary disease	
	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	Tablet

		yeast infections of the skin caused by the genus candida	
		Onychomycosis of the toenail or fingernail due to dermatophytes	
Lescol and *Lescol XL*	fluvastatin sodium	Hypercholesterolemia and mixed dyslipidemia in adults	Capsule (*Lescol)* Tablet (*Lescol XL*)
		Secondary prevention of major adverse cardiac events	
		Slowing the progression of atherosclerosis	
		Heterozygous familial hypercholesterolemia in children and adolescents	
Reclast/Aclasta	zoledronic acid 5 mg	Treatment of osteoporosis in postmenopausal women	Intravenous solution for infusion
		Treatment of osteoporosis in men Treatment and prevention of glucocorticoid-induced osteoporosis	
		Prevention of postmenopausal osteoporosis	
		Treatment of Paget's disease of the bone	

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Ritalin	methylphenidate HCl	Attention deficit hyperactivity disorder and narcolepsy	Tablet
	Ritalin LA	methylphenidate HCl modified release	Attention deficit hyperactivity disorder	Capsule
	Tegretol	carbamazepine	Epilepsy Pain associated with trigeminal neuralgia Acute mania and bipolar affective disorders Alcohol withdrawal syndrome Painful diabetic neuropathy Diabetes insipidus centralis Polyuria and polydipsia of neurohormonal origin	Tablet Chewable tablet Oral suspension Suppository
	Tekamlo/Rasilamlo	aliskiren and amlodipine besylate	Hypertension	Tablet
	Tekturna/Rasilez	aliskiren	Hypertension	Tablet
	Tekturna HCT/ Rasilez HCT	aliskiren and hydrochlorothiazide	Hypertension	Tablet
	Trileptal	oxcarbazepine	Epilepsy	Tablet Oral suspension
	Tyzeka/Sebivo	telbivudine	Chronic hepatitis B	Tablet Oral solution
	Vivelle-Dot/Estradot	estradiol hemihydrate	Estrogen replacement therapy for the treatment of the symptoms of natural or surgically induced menopause Prevention of postmenopausal osteoporosis	Transdermal patch
	Voltaren/Cataflam	diclofenac sodium/potassium/resinate/free acid	Inflammatory and degenerative forms of rheumatism Post traumatic and post-operative pain, inflammation and swelling	Tablet Capsule Oral drops/oral suspension Ampoule for injection Suppository Gel Powder for oral solution Transdermal patch

	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

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 more than 65 countries as a post-surgery (adjuvant setting) therapy for certain adult patients with KIT+ GIST. Following approval by the FDA in 2013, the EMA approved *Gleevec/Glivec* in July 2013 for pediatric patients with newly diagnosed Ph+ acute lymphoblastic leukemia in combination with chemotherapy.

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Afinitor/Votubia and *Afinitor Disperz/Votubia* dispersible tablets (everolimus) is an oral inhibitor of the mTOR pathway. *Afinitor* is approved in more than 120 countries including the US, EU member states and Japan for advanced renal cell carcinoma following vascular endothelial growth factor-targeted therapy (in the US, after failure of sunitinib or sorafenib). *Afinitor* is also approved in more than 95 countries, including the US, EU member states and Japan for the treatment of advanced pancreatic neuroendocrine tumors. In addition, *Afinitor* is approved in more than 100 countries for advanced hormone receptor-positive, HER2-negative (HR+/HER2) breast cancer in combination with the drug exemestane. Everolimus is also approved in more than 95 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 90 countries for the treatment of adult patients with renal angiomyolipomas and TSC who do not require immediate surgery. *Afinitor Disperz,* the dispersible tablet for oral suspension formulation of *Afinitor*, is approved for the TSC-SEGA population in several countries including the US and Japan. *Votubia* dispersible tablets are approved for the treatment of patients with TSC-SEGA in the EU member states. 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.

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 more than 60 countries for treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary tumor location. More than 65 countries have also approved an enhanced presentation of *Sandostatin LAR*, which includes a diluent, safety needle and vial adapter. *Sandostatin* was first launched in 1988 and is approved in more than 100 countries.

Exjade and *Jadenu* (deferasirox) is an iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older as well as chronic iron overload in patients with non-transfusion-dependent thalassemia. *Exjade* is a dispersible tablet for oral suspension. *Jadenu* is an oral tablet formulation of *Exjade* that can be swallowed or crushed and was approved by the FDA in 2015. Patients with chronic anemia from diseases such as thalassemia, sickle cell disease and myelodysplastic syndromes require repeated 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 for *Jadenu* have been submitted in the EU, Canada, Switzerland and other countries.

Votrient (pazopanib) is a small molecule tyrosine kinase inhibitor that targets a number of intracellular proteins to limit tumor growth and cell survival. *Votrient* is approved in the US for the treatment of patients with advanced renal cell carcinoma (aRCC), and in the EU for first-line treatment of adult patients with aRCC and for patients who have received prior cytokine therapy

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for advanced disease. RCC is the most common type of kidney cancer in adults, and nearly one-fifth of patients have aRCC at the time of diagnosis. *Votrient* is also indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy (efficacy in adipocytic STS or gastrointestinal stromal tumors has not been demonstrated). STS is a type of cancer which can arise from a wide variety of soft tissues including muscle, fat, blood vessel and nerves. *Votrient* is approved in more than 95 countries worldwide for aRCC and in more than 85 countries for aSTS. *Votrient* was acquired from GSK.

Tafinlar + *Mekinist* (dabrafenib + trametinib) is the first combination of its kind for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma, as detected by a validated test, in the US, EU and several other markets. In November 2015, the FDA granted regular approval for the combination of *Tafinlar* + *Mekinist* for the treatment of patients with BRAF V600E/K mutation-positive unresectable or metastatic melanoma as detected by an FDA-approved test. In August 2015, the combination of *Tafinlar* and *Mekinist* was approved in Europe for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. *Tafinlar* targets the serine/threonine kinase BRAF in the RAS/RAF/MEK/ERK pathway and *Mekinist* targets the threonine/tyrosine kinases MEK1 and MEK2 in the MAP kinase pathway, resulting in dual blockade of this pathway. This is the first combination of BRAF/MEK inhibitors to achieve a median overall survival of more than two years in two Phase III studies in BRAF V600 mutation positive unresectable or metastatic melanoma patients. *Tafinlar* and *Mekinist* are each also approved as single agents for the treatment of patients with unresectable or metastatic melanoma in more than 45 and 30 countries worldwide, respectively. *Tafinlar* and *Mekinist* were each acquired from GSK. As part of our purchase of oncology products from GSK, we obtained the worldwide exclusive rights granted by Japan Tobacco Inc. (JT) to develop, manufacture, and commercialize trametinib.

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 and adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. *Jakavi* is currently approved in more than 95 countries for patients with myelofibrosis, including EU member states, Japan, Canada, Australia, Mexico and Argentina. *Jakavi* is approved for the polycythemia vera indication in more than 45 countries, including Switzerland, Japan and Canada. Worldwide regulatory filings are ongoing in different regions for myelofibrosis and polycythemia vera. In the COMFORT-II Phase III study, five-year treatment with *Jakavi* demonstrated an overall survival advantage for myelofibrosis patients, despite crossover from best available therapy after week 48. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US. Ruxolitinib, marketed in the US as Jakafi® by Incyte Corporation, is approved by the FDA 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.

Promacta/Revolade (eltrombopag) is a once-daily oral thrombopoietin (TPO) receptor agonist that works by stimulating bone marrow cells to produce platelets. It is the only approved once-daily oral thrombopoietin receptor agonist, and is marketed under the brand name *Promacta* in the US and *Revolade* in most countries outside the US. In the US, *Promacta* is approved for the treatment of thrombocytopenia in adult and pediatric patients one year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. In August 2015, the FDA approved an oral suspension formulation of *Promacta* that is designed for younger children with chronic ITP who may not be able to swallow tablets. *Promacta* is also approved for the treatment of thrombocytopenia in

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patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy, and for the treatment of patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppressive therapy. *Revolade* is approved in more than 100 countries worldwide for the treatment of adult chronic ITP splenectomised patients who are refractory to other treatments (e.g., corticosteroids, immunoglobulins). *Revolade* may be considered as second line treatment for adult non-splenectomised patients where surgery is contraindicated. In December 2015, the CHMP adopted a positive opinion recommending a change to the adult ITP indication to remove language which limited *Revolade* use only to splenectomised patients who are refractory to other treatments. The EC decision is expected in February 2016. *Revolade* is also indicated in more than 45 countries worldwide in adult patients with chronic hepatitis C virus infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. In September 2015, *Revolade* was approved by the EC for the treatment of adults with acquired SAA who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for hematopoietic stem cell transplant. *Promacta/Revolade* is marketed under a collaboration agreement between Ligand Pharmaceuticals, Inc., and Novartis. *Promacta/Revolade* was acquired from GSK.

Farydak (panobinostat), previously known as LBH589, is a histone deacetylase (HDAC) inhibitor indicated, in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent. *Farydak* marks the first time an HDAC inhibitor with epigenetic activity is available to patients with multiple myeloma and provides an additional treatment option for patients whose disease has progressed after standard-of-care therapy. *Farydak* in combination with bortezomib and dexamethasone was approved in 2015 in the US, EU and Japan for certain patients with previously treated multiple myeloma. The exact indication for *Farydak* varies by country. Additional regulatory submissions for *Farydak* are being reviewed by health authorities worldwide. Results from the pivotal Phase III PANORAMA-1 study of *Farydak* in combination with bortezomib and dexamethasone in patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent, were published online in the journal Blood and showed a progression free survival benefit favoring the *Farydak* combination.

Odomzo (sonidegib), previously known as LDE225, is a selective smoothened inhibitor approved in the US in July 2015 for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. In addition, the EC approved *Odomzo* in August 2015 for the treatment of adult patients with laBCC who are not amenable to curative surgery or radiation therapy.

Cardio-Metabolic

Galvus (vildagliptin), an oral DPP-4 inhibitor, and *Eucreas*, a vildagliptin and metformin single-pill combination, are indicated for the treatment of type 2 diabetes. The products were first approved in 2007. *Galvus* is currently approved in more than 130 countries, including EU member states, Japan (as *Equa*) and countries in Latin America and Asia-Pacific. *Eucreas* was the first single-pill combination of a DPP-4 inhibitor and metformin approved in Europe, and also under the trade name *Galvus Met*, and is currently approved in more than 125 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 2012, the EC 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

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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. In 2014, *Eucreas* (850/50mg and 1000/50mg) was approved in China as the first high-dose single-pill combination metformin/DPP-4 inhibitor approved in that country. *Galvus* monotherapy indication was approved in China in April 2015. *Eucreas* was approved in Japan in September 2015 under the name *EquMet* as the first single-pill combination metformin/DPP-4 inhibitor approved in that country.

Entresto (sacubitril/valsartan), previously known as LCZ696, is a first-in-class angiotensin receptor/neprilysin inhibitor indicated for the treatment of chronic heart failure with reduced ejection fraction (HFrEF). It 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). *Entresto* was approved and launched in the US in July 2015 as a treatment for HFrEF. In September 2015, the Swiss health authority approved *Entresto* to reduce the risk of cardiovascular mortality and morbidity in patients with HFrEF. In November 2015, *Entresto* was approved in the EU for the treatment of adult patients with symptomatic HFrEF. PARAGON-HF, a Phase III trial of *Entresto* in patients with chronic heart failure with preserved ejection fraction is underway.

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 approximately 100 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. 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 more than 70 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,

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occasional 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 more than 40 other countries as a treatment for chronic spontaneous urticaria (CSU)/chronic idiopathic urticaria (CIU) including approvals in the EU 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. We co-promote *Xolair* with Genentech 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 monoclonal antibody that selectively neutralizes circulating interleukin 17A (IL-17A). 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 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 as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. In addition to the EU and US, *Cosentyx* has been approved and launched in Switzerland, Canada, Australia and various other markets for the treatment of moderate-to-severe plaque psoriasis. In November 2015, *Cosentyx* was approved in the EU for the treatment of adults with ankylosing spondylitis who have responded inadequately to conventional therapy, such as non-steroidal anti-inflammatory drugs, and for the treatment of active psoriatic arthritis in adults when the response to disease modifying anti-rheumatic drug therapy is unsatisfactory. In Japan, *Cosentyx* is approved for the treatment of moderate-to-severe plaque psoriasis as well as PsA. In December 2015, the Japanese MHLW approved *Cosentyx* for the treatment of patients with pustular psoriasis. In January 2016, *Cosentyx* was approved in the US for the treatment of adults with active ankylosing spondylitis and for the treatment of adults with active psoriatic arthritis.

Retina

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors (VEGF). It is an anti-VEGF therapy licensed in many countries for five ocular indications: neovascular age-related macular degeneration (nAMD), visual impairment due to diabetic macular edema (DME), visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO), visual impairment due to macular edema secondary to central retinal vein occlusion (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 nAMD, for the treatment of visual impairment due to DME and macular edema secondary to RVO. Also, *Lucentis* is licensed in more than 80 countries for the treatment of visual impairment due to myopic CNV. *Lucentis* is the only anti-VEGF treatment available in a pre-filled syringe. Since its launch in 2007, there have been more than 3.7 million patient-treatment years of exposure for *Lucentis* and more than 22 million injections. We licensed *Lucentis* from Genentech for development and commercialization outside of the US. See "Item 18. Financial Statements Note 27" for further information.

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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. *Xolair* was submitted to the FDA in December 2015 for pediatric allergic asthma. See also, *Xolair* in "Immunology and Dermatology" above.

Ultibro Breezhaler (indacaterol/glycopyrronium bromide) / *Utibron Neohaler* (indacaterol/glycopyrrolate) is a fixed-dose combination of the long-acting beta$_2$-adrenergic agonist (LABA) indacaterol and the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide. *Ultibro Breezhaler* (indacaterol 85 mcg/glycopyrronium 43 mcg), inhalation powder, hard capsules was approved in the EU in 2013 as a once-daily 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 low resistance *Breezhaler* inhalation device, for relief of various symptoms due to airway obstruction in COPD (chronic bronchitis, emphysema). In October 2015 the combination was approved in the US under the name *Utibron Neohaler* (indacaterol 27.5 mcg/glycopyrrolate 15.6 mcg) as a twice-daily dual bronchodilator for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. The combination is approved in more than 80 countries and launched in more than 40 countries. The LAMA glycopyrronium bromide is approved individually as once-daily *Seebri Breezhaler* in the EU, *Seebri* (glycopyrronium) Inhalation Capsules 50 mcg administered through the *Breezhaler* device in Japan, and twice-daily *Seebri Neohaler* in the US, where the active ingredient is known as glycopyrrolate. It is now approved in more than 90 countries worldwide. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Vectura Group plc and its co-development partner Sosei. The LABA indacaterol is approved individually as once-daily *Onbrez Breezhaler* in the EU, *Onbrez* Inhalation Capsules delivered through the *Breezhaler* inhalation device in Japan, and *Arcapta Neohaler* in the US. It is now approved in more than 100 countries worldwide.

Neuroscience

Gilenya (fingolimod) is the first oral therapy approved to treat relapsing forms of multiple sclerosis (RMS) 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 to impact the course of RMS with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. As of November 2015, more than 130,000 patients have been treated in clinical trials and in a post-marketing setting, with more than 285,000 total patient-years of exposure. *Gilenya* is currently approved in more than 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

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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 2013, the FDA expanded the approved indication for *Exelon Patch* to also include the treatment of patients with severe Alzheimer's disease. In 2013, European Marketing Authorization was obtained for the higher dose in mild-to-moderate AD. The higher dose has been approved in more than 50 countries. In 2013, the FDA expanded the approved indication for *Exelon Patch* to also include the treatment of patients with severe Alzheimer's disease. The severe indication has now been approved in more than 10 countries.

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 October 2015; 58 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 more than 100 countries worldwide. *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. *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 75 countries.

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, and our Alcon Division markets *Voltaren* for ophthalmic indications. In addition, we have licensed the *Voltaren* trademarks to our consumer healthcare joint venture with GSK to be used in the marketing of low dose oral forms and the topical forms 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 more than 70 countries. *Ritalin LA* is available in more than 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.

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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.

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.

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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**
ABL001	TBD	BCR-ABL inhibitor	Chronic myeloid leukemia	Oncology	Oral	2015	≥2020/I
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	Subcutaneous injection	2011	2017/III
Afinitor/Votubia (RAD001)	everolimus	mTOR inhibitor	Non-functioning GI and lung neuroendocrine tumors	Oncology	Oral	2015	US/EU (registration)
			Tuberous sclerosis complex seizures	Oncology	Oral	2013	2016/III
			Diffuse large B-cell lymphoma	Oncology	Oral	2009	2016/III
AMG 334	TBD	Selective CGRP receptor antagonist	Migraine	Neuroscience	Subcutaneous injection	2015	III
Arzerra	ofatumumab	Anti-CD20 monoclonal antibody	Chronic lymphocytic leukemia (extended treatment)	Oncology	Intravenous infusion	2015	EU (registration) US (approved)
			Chronic lymphocytic leukemia (relapse)	Oncology	Intravenous infusion	2009	2016/III
			Refractory non-Hodgkin's lymphoma	Oncology	Intravenous infusion	2010	2017/III
ASB183	afuresertib	AKT inhibitor	Solid and hematologic tumors	Oncology	Oral	2011	≥ 2020/I
BAF312	siponimod	Sphingosine-1-phosphate receptor modulator	Secondary progressive multiple sclerosis	Neuroscience	Oral	2012	2019/III
BGJ398	infigratinib	Pan-FGF receptor kinase inhibitor	Solid tumors	Oncology	Oral	2012	≥ 2020/II
BKM120	buparlisib	PI3K inhibitor	Metastatic breast cancer, hormone receptor-positive, aromatase	Oncology	Oral	2011	2016/III

			inhibitor resistant/mTOR naïve, 2nd line (+ fulvestrant)				
			Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor resistant, 3rd line (+ fulvestrant)	Oncology	Oral	2011	2016/III
			Solid tumors	Oncology	Oral	2011	≥ 2020/I
BYL719	alpelisib	PI3Kα inhibitor	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 2nd line (+ fulvestrant)	Oncology	Oral	2015	2019/III
			Solid tumors	Oncology	Oral	2010	≥2020/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
BYM338	bimagrumab	Inhibitor of activin receptor Type II	Sporadic inclusion body myositis	Neuroscience	Intravenous infusion	2013	2016/III
			Hip fracture	Neuroscience	Intravenous infusion	2013	≥2020/II
			Sarcopenia	Neuroscience	Intravenous infusion	2014	≥2020/II
CAD106	TBD	Beta-amyloid-protein therapy	Alzheimer's disease	Neuroscience	Intramuscular injection	2008	≥2020/ II/III
CJM112	TBD	Anti-IL-17 monoclonal antibody	Immune disorders	Immunology and Dermatology	Subcutaneous injection	2015	≥2020/II
CNP520	TBD	BACE inhibitor	Alzheimer's Disease	Neuroscience	Oral	2015	≥2020/ I/II
Cosentyx (AIN457)	secukinumab	Anti-IL-17 monoclonal antibody	Non-radiographic axial spondyloarthritis	Immunology and Dermatology	Subcutaneous injection	2015	2018/III
CTL019	tisagenlecleucel-T	CD19-targeted chimeric antigen receptor T-cell immunotherapy	Pediatric acute lymphoblastic leukemia	Cell and Gene Therapies	Intravenous	2012	2017/II
			Diffuse large B-cell lymphoma	Cell and Gene Therapies	Intravenous	2014	2017/II
EGF816	TBD	Epidermal growth factor receptor inhibitor	Solid tumors	Oncology	Oral	2014	2018/ I/II
EMA401	TBD	Angiotensin II receptor antagonist	Neuropathic Pain	Neuroscience	Oral	2011	≥2020/II
Entresto (LCZ696)	valsartan and sacubitril (as sodium salt complex)	Angiotensin receptor/ neprilysin inhibitor	Chronic heart failure with preserved ejection fraction	Cardio-Metabolic	Oral	2013	2019/III
			Post-acute myocardial infarction	Cardio-Metabolic	Oral	2015	≥ 2020/III
Exjade film-coated tablet (FCT)	deferasirox	Iron chelator	Iron overload	Oncology	Oral film-coated tablet	2015	EU (registration) US (approved as *Jadenu*)
FCR001	TBD	Inducing stable donor chimerism and immunological tolerance	Renal transplant	Cell and Gene Therapies	Intravenous	2009	≥2020/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	Intravenous	2012	≥2020/II
INC280	capmatinib	c-MET inhibitor	Non-small cell lung cancer	Oncology	Oral	2013	2018/II
KAE609	cipargamin	PfATP4 inhibitor	Malaria	Established Medicines	Oral	2012	≥2020/II
KAF156	TBD	Imidazolopiperazines derivative	Malaria	Established Medicines	Oral	2013	2019/II
LCI699	osilodrostat	Aldosterone synthase inhibitor	Cushing's disease	Oncology	Oral	2011	2017/III
LEE011	ribociclib	CDK4/6 inhibitor	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 1st line (+ letrozole)	Oncology	Oral	2013	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
			Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 1st/2nd line (+ fulvestrant)	Oncology	Oral	2015	2018/III
			Hormone receptor-positive, HER2 negative advanced breast cancer (premenopausal women), 1st line, (+ tamoxifen + goserelin or NSAI + goserelin)	Oncology	Oral	2014	2018/III
			Solid tumors	Oncology	Oral	2011	≥2020/I
LJM716	elgemtumab	HER3 monoclonal antibody	Solid tumors	Oncology	Intravenous infusion	2012	≥2020/I
LJN452	TBD	FXR agonist	Non-alcoholic steatohepatitis	Immunology and Dermatology	Oral	2015	≥2020/II
Lucentis	ranibizumab	Anti-VEGF monoclonal antibody fragment	Choroidal neovascularization secondary to conditions other than age-related macular degeneration and pathologic myopia	Retina	Intravitreal injection	2013	2016/III
			Retinopathy of Prematurity	Retina	Intravitreal injection	2014	2018/III
OAP030 (also known as *Fovista* / E10030)	pegpleranib	Aptamer anti-platelet-derived growth factor (PDGF)	Neovascular age-related macular degeneration	Retina	Solution	2013	2017/III
OMB157	ofatumumab	Anti-CD-20 monoclonal antibody	Relapsing multiple sclerosis	Neuroscience	Subcutaneous injection	2008	2019/II
PIM447	TBD	Pan-PIM inhibitor	Hematologic tumors	Oncology	Oral	2015	≥2020/I
PKC412	midostaurin	Signal transduction inhibitor	Acute myeloid leukemia	Oncology	Oral	2008	2016/III
				Oncology	Oral	2008	2016/II

			Aggressive systemic mastocytosis				
Promacta/ Revolade	eltrombopag	Thrombopoietin receptor agonist	Pediatric immune thrombocytopenia	Oncology	Oral and oral suspension	2015	EU (registration) US (approved)
QAW039	fevipiprant	CRTH2 antagonist	Asthma	Respiratory	Oral	2010	2019/III
			Atopic dermatitis	Immunology and Dermatology	Oral	2013	≥2020/II
QAX576	TBD	Anti-interleukin-13 monoclonal antibody	Allergic diseases	Immunology and Dermatology; Respiratory	Subcutaneous injection	2013	≥2020/II
QGE031	ligelizumab	High affinity anti-IgE monoclonal antibody	Chronic spontaneous urticaria/ Inducible urticaria	Immunology and Dermatology	Subcutaneous injection	2015	≥2020/II
QMF149	indacaterol, mometasone furoate (in fixed dose combination)	Long-acting beta2-adrenergic agonist and inhaled corticosteroid	Asthma	Respiratory	Inhalation	2015	2018/III
QVM149	indacaterol, mometasone furoate, glycopyrronium bromide (in fixed dose combination)	Long-acting beta2-adrenergic agonist, Long-acting muscarinic antagonist and inhaled corticosteroid	Asthma	Respiratory	Inhalation	2015	2018/III
RLX030	serelaxin	Recombinant form of human relaxin-2 hormone	Acute heart failure	Cardio-Metabolic	Intravenous infusion	2009	2017/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**
Signifor LAR (SOM230)	pasireotide	Somatostatin analogue	Cushing's disease	Oncology	Long-acting release/ intramuscular injection	2011	2016/III
Tafinlar+Mekinist	dabrafenib + trametinib	BRAF inhibitor + MEK inhibitor	BRAF V600+ non-small cell lung cancer	Oncology	Oral	2011	2016/II
			BRAF V600+ melanoma (adjuvant)	Oncology	Oral	2013	2017/III
			BRAF V600+ colorectal cancer	Oncology	Oral	2012	≥ 2020/ I/II
Tasigna	nilotinib	BCR-ABL inhibitor	Chronic myeloid leukemia treatment-free remission	Oncology	Oral	2012	2016/III
VAY736	TBD	Anti BAFF (B-cell activating factor) antibody	Primary Sjoegren's syndrome	Immunology and Dermatology	Subcutaneous injection	2015	≥2020/II
Votrient	pazopanib	Angiogenesis inhibitor	Renal cell carcinoma (adjuvant)	Oncology	Oral	2010	2016/III
Zykadia (LDK378)	ceritinib	ALK inhibitor	ALK + advanced non-small cell lung cancer (first line, treatment naïve)	Oncology	Oral	2013	2017/III
			ALK + advanced non-small cell lung cancer (brain metastases)	Oncology	Oral	2015	2019/II

Key Development Projects

ACZ885 (canakinumab) was first approved in 2009 for cryopyrin associated periodic syndrome (CAPS) as *Ilaris*. Since then, *Ilaris* has been approved in the EU in 2013 for the treatment of acute attacks in gouty arthritis and 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 fully enrolled 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/Votubia and *Afinitor Disperz* (RAD001, everolimus) is an oral inhibitor of the mTOR pathway. Phase III studies are underway in patients with advanced breast cancer and diffuse large B-cell lymphoma (PILLAR-2). 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 pivotal Phase III RADIANT-4 (RAD001 In Advanced Neuroendocrine Tumors) trial were presented in 2015 at a European medical congress and showed that *Afinitor* reduced the risk of progression by 52% versus placebo in patients with advanced, progressive, nonfunctional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin. The safety results were in line with the known safety profile of *Afinitor*. In October 2015, the FDA granted priority review to *Afinitor* for use in advanced, progressive, non-functional neuroendocrine tumors of gastrointestinal or lung origin. Results from the RADIANT-4 trial were published in The Lancet in December 2015.

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AMG 334 is a fully human monoclonal antibody which is part of a new class of compounds targeting Calcitonin-Gene-Related-Peptide (CGRP) being investigated for the prevention of migraine. AMG 334 inhibits the activity of CGRP by targeting its receptor, which is believed to transmit signals to cause the pain associated with migraine. Data announced in May 2015 showed that AMG 334 met its primary endpoint of reduction of monthly mean migraine days compared with placebo in a Phase II trial for the prevention of episodic migraine. AMG 334 is currently being evaluated in a large global Phase II trial in the prevention of chronic migraine and in two large global Phase III studies to further assess its safety and efficacy in the prevention of episodic migraine. Novartis and Amgen entered into a collaboration agreement in August 2015 with respect to the development and commercialization of Amgen's proprietary monoclonal antibody AMG 334.

Arzerra (ofatumumab) is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of chronic lymphocytic leukemia (CLL) cells and normal B lymphocytes. In 2015, results from the Phase III COMPLEMENT 2 study showed that treatment with ofatumumab plus fludarabine and cyclophosphamide significantly improved median progression-free survival by 54% compared to treatment with fludarabine and cyclophosphamide alone in patients with relapsed CLL. In addition, results from the Phase III PROLONG study evaluating ofatumumab maintenance therapy versus no further treatment (observation) in patients with relapsed CLL who responded to induction treatment at relapse formed the basis for submissions made in 2015 to the EMA and FDA for this indication. In September 2015, the FDA granted Priority Review for ofatumumab as maintenance therapy in relapsed CLL, and in January 2016 the FDA approved *Arzerra* for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. A Phase III trial is also underway to investigate ofatumumab in refractory non-Hodgkin's lymphoma. In November 2015, Genmab announced that the Phase III study of single-agent ofatumumab compared to single-agent rituximab in patients with follicular non-Hodgkin's lymphoma that has relapsed at least six months after completion of treatment with a rituximab-containing regimen will be stopped early. The decision to stop the study was made after a planned interim analysis performed by an independent data monitoring committee showed that it was unlikely that ofatumumab would show superiority if the trial were to be completed as planned. *Arzerra* is marketed under a license agreement between Genmab and Novartis. *Arzerra* for oncology indications was acquired from GSK as part of the previously-announced portfolio transformation transactions. In December 2015, we acquired all remaining rights from GSK to develop ofatumumab for multiple sclerosis and other autoimmune indications, disclosed as OMB157.

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

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with other agents, including two Phase III trials in hormone receptor-positive (HR+) advanced breast cancer. Results from the Phase III BELLE-2 trial of BKM120 in patients with HR+, HER2 negative advanced breast cancer were presented in December 2015 at a US breast cancer symposium. In this trial, BKM120 plus fulvestrant led to 6.9 months of progression free survival compared to 5.0 months for placebo plus fulvestrant, a statistically significant difference. The subpopulation of patients with ctDNA PIK3CA mutation experienced a 3.8 month progression-free survival improvement when adding BKM120 to fulvestrant compared to the placebo plus fulvestrant arm. The results of this trial are being discussed with regulatory authorities.

BYL719 (alpelisib) is an orally bioavailable, alpha isoform-specific PI3K inhibitor. In breast cancer cell lines harboring PIK3CA mutations, BYL719 has been shown to inhibit the PI3K/AKT/mTOR pathway and have anti-proliferative effects. In addition, cancer cell lines with PIK3CA mutations were more sensitive to alpelisib than those without the mutation across a broad range of different cancers. BYL719 is in a Phase III study in hormone receptor-positive advanced breast cancer.

BYM338 (bimagrumab) is a novel, human monoclonal antibody in development to treat sporadic inclusion body myositis (sIBM). In 2013, FDA granted Breakthrough Therapy designation to BYM338 for sIBM, and we initiated a Phase II/III study of bimagrumab in patients with sIBM. This study showed that in sIBM patients, a single dose of bimagrumab improved muscle volume at eight weeks (muscle volume for right leg increased 6.5% compared to placebo) and walking distance at 16 weeks. BYM338 binds with high affinity to activin type II 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 acute and chronic muscle-wasting conditions, including recovery from hip fracture and sarcopenia. BYM338 was developed by Novartis, in collaboration with MorphoSys.

Cosentyx (secukinumab) is a fully human monoclonal antibody that selectively neutralizes circulating IL-17A. In January 2016, *Cosentyx* was approved by the FDA for the treatment of adults with ankylosing spondylitis (AS) and for the treatment of adults with psoriatic arthritis (PsA). Results for *Cosentyx* presented at a US medical meeting showed up to 80% of patients with AS had no radiographic progression in the spine as shown by x-ray assessment over two years. This is the first time that data on structural spinal progression in AS have been presented for an IL-17A inhibitor. At the same meeting, new data was also presented showing no further progression in joint damage in 84% of patients with PsA over two years of treatment. In addition, the results of the MEASURE 1 and MEASURE 2 Phase III studies for *Cosentyx* in AS were published in the New England Journal of Medicine in December 2015. These pivotal studies demonstrated significant clinical improvements with *Cosentyx* versus placebo in the signs and symptoms of active AS, and collectively, the studies form the largest clinical trial program ever conducted in AS, involving 590 patients. Secukinumab is also in Phase III development for non-radiographic axial spondyloarthritis.

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. The latest findings from two ongoing Phase II studies of CTL019 were presented in December 2015 at the American Society of Hematology annual meeting. In a study of relapsed/refractory pediatric acute lymphoblastic leukemia, 55 of 59 patients experienced complete remissions with CTL019. Overall survival was 79% at 12 months and relapse-free survival was 76% at six months and 55% at 12 months. Additionally, 52 of 59 patients developed Grade 1 4 cytokine-release syndrome. In a study of CTL019 in certain relapsed/refractory non-Hodgkin

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lymphomas, an overall response rate of 73% (8/11) was observed in patients with follicular lymphoma and an overall response rate of 47% (7/15) in patients with diffuse large B-cell lymphoma. Four patients developed cytokine-release syndrome of grade 3 or higher at peak T cell expansion.

EMA401 is a novel angiotensin II Type 2 receptor (AT_2R) antagonist in Phase II development. Targeting AT_2R is an emerging approach to neuropathic pain treatment. AT_2R antagonists block the pain signaling pathways in the peripheral nervous system. Positive results from a Phase II clinical trial of EMA401 in post-herpetic neuralgia, a painful condition that develops in some people following herpes zoster (shingles), were published in a major medical journal in February 2014. In addition, thus far, EMA401 has not been associated with central nervous system side effects such as dizziness or confusion, which are typically associated with existing therapies.

Entresto (sacubitril/valsartan), previously known as LCZ696, is a first-in-class angiotensin receptor/neprilysin inhibitor approved and marketed for the treatment of chronic heart failure with reduced ejection fraction (HFrEF). In addition, Novartis is conducting two large outcome studies. The first, PARAGON-HF, a Phase III trial of *Entresto* in patients with chronic heart failure with preserved ejection fraction is underway, and the second, PARADISE-HF, in patients at high risk for heart failure after a myocardial infarction (MI) is about to start.

Gilenya (fingolimod) is a sphingosine 1-phosphate receptor modulator approved for the treatment of relapsing forms of multiple sclerosis. A Phase III study of fingolimod in patients with chronic inflammatory demyelinating polyradiculoneuropathy was initiated in 2012. Submissions to health authorities in this indication are anticipated in 2017.

LEE011 (ribociclib) is an orally bioavailable, highly selective small molecule inhibitor of cyclin dependent kinase (CDK) 4 and 6. The compound is in Phase III registration studies in hormone receptor-positive advanced breast cancer with results expected in 2016. LEE011 is also in Phase I and II investigation, with a number of ongoing studies in solid tumors. LEE011 was discovered by Novartis as part of a drug discovery collaboration with Astex Pharmaceuticals.

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

OAP030 (pegpleranib; also known as *Fovista* and E10030) 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 neovascular age-related macular degeneration (AMD). The second Phase III trial of pegpleranib in combination with *Lucentis* for the treatment of neovascular age-related macular degeneration (nAMD) completed enrollment in October 2015. Initial top-line data from the OAP030 Phase III clinical program are expected to be available in 2016. In November 2015, Genentech entered into an agreement with Novartis to participate in certain rights related to the Novartis licensing and commercialization agreement with Ophthotech Corporation for OAP030. We continue to hold the license for the exclusive rights to develop and market OAP030 outside the US and will remain responsible for the development and commercialization for OAP030 outside of the US. Genentech will share certain risks and benefits with Novartis.

OMB157 (ofatumumab) is a fully human monoclonal antibody administered by subcutaneous injection in development for MS. OMB157 works by binding to the CD20 molecule on the B cell surface and inducing B cell depletion. Positive phase IIb results in MS patients were presented in

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2014 and showed significant reduction in the number of new brain lesions in the first 24 weeks after ofatumumab administration. Novartis plans to initiate a Phase III program for OMB157 in MS in 2016. We expect to make regulatory filings in MS in 2019. Ofatumumab is marketed by Novartis for oncology indications under the brand name *Arzerra*.

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) and mast cell leukemia (MCL). The pivotal Phase III RATIFY study of newly-diagnosed AML patients aged 18 to under 60 who have a FLT3 mutation was presented at a major US congress in 2015. In the RATIFY study, patients who received PKC412 plus standard induction and consolidation chemotherapy experienced a 23% improvement in overall survival compared to those treated with standard induction and consolidation chemotherapy alone. The median overall survival for patients in the PKC412 treatment group was 74.7 months, versus 26.0 months for patients in the placebo group. This study evaluated the addition of either PKC412 or placebo to daunorubicin/cytarabine in the induction phase, followed by high-dose cytarabine in the consolidation phase. Patients who achieved complete remission after consolidation chemotherapy continued treatment with PKC412 or placebo as a single agent for up to one year. PKC412 is the first compound to illustrate an overall survival benefit targeting FLT3 in AML. These data are expected to form the basis for regulatory filings for PKC412 in newly diagnosed FLT3 mutated AML. Filings are expected for newly diagnosed, FLT3-mutated AML and for ASM/MCL in 2016.

Promacta/Revolade (eltrombopag) is a once-daily oral thrombopoietin receptor agonist that works by stimulating bone marrow cells to produce platelets. *Promacta/Revolade* is currently under review in the EU for pediatric immune thrombocytopenia. Phase II and III studies to investigate eltrombopag in myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) associated thrombocytopenia do not support registration of *Promacta/Revolade* in intermediate-1, 2 and high risk MDS and/or AML. We are evaluating the data from both trials to assess whether ongoing development of *Promacta/Revolade* in these patient populations is warranted.

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 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. Following interim analysis, the Data Monitoring Committee of the RELAX-AHF-2 study recommended continuing the serelaxin RELAX-AHF-2 trial without changes. Top-line results are expected in 2017, after study completion based on a pre-specified number of cardiovascular events. RLX030 received regulatory approval from the Ministry of Health in Russia in 2014 and is launched there under the trade name *Reasanz*.

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.

Tafinlar (dabrafenib) targets the serine/threonine kinase BRAF in the RAS/RAF/MEK/ERK pathway and *Mekinist* (trametinib) targets the threonine/tyrosine kinases MEK1 and MEK2 in the

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MAP kinase pathway, resulting in dual blockade of this pathway, which is the main escape mechanism for resistance. Phase II studies are underway to evaluate the efficacy and safety of *Tafinlar* + *Mekinist* in patients with BRAF V600 mutation positive non-small cell lung cancer (NSCLC). *Tafinlar* has a Breakthrough Therapy designation from the FDA for treatment of NSCLC patients with BRAF V600E mutations who have received at least one prior line of platinum-containing chemotherapy. In July 2015, the combination therapy *Tafinlar* + *Mekinist* also received Breakthrough Therapy designation from the FDA for NSCLC patients with BRAF V600E mutations. A Phase III study is also underway for BRAF V600 mutation positive melanoma patients in the adjuvant setting. Results from a pooled data analysis showed that patients with BRAF V600E/K mutation-positive unresectable or metastatic melanoma treated with *Tafinlar* + *Mekinist* experienced longer progression-free survival and overall survival when baseline lactate dehydrogenase (LDH) levels were normal compared to those with elevated LDH levels, further validating the combination for BRAF positive patients with a better prognosis (indicated by a normal LDH level).

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.

Votrient (pazopanib) is a small molecule tyrosine kinase inhibitor that targets a number of intracellular proteins to limit tumor growth and cell survival. A phase III trial (PROTECT) is underway to evaluate *Votrient* for the adjuvant treatment of patients with localized or locally advanced renal cell carcinoma following nephrectomy.

Zykadia (LDK378, ceritinib) is a potent and highly selective oral anaplastic lymphoma kinase (ALK) inhibitor that is in development for ALK positive (ALK+) cancers. 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.

Projects Added To And Subtracted From The Development Table Since 2014

Project/Product	**Potential indication/ Disease area**	**Change**	**Reason**
ABL001	Chronic myeloid leukemia	Added	Entered Confirmatory Development
AMG 334	Migraine	Added	Collaboration with Amgen announced in September 2015
Arzerra	Chronic lymphocytic leukemia (extended treatment)	Added	Acquired from GSK
	Chronic lymphocytic leukemia (relapse)	Added	Acquired from GSK
	Refractory non-Hodgkin's lymphoma	Added	Acquired from GSK

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Project/Product	Potential indication/ Disease area	Change	Reason
ASB183	Solid and hematologic tumors	Added	Acquired from GSK
BCT197	Chronic obstructive pulmonary disease	Removed	Transferred to Mereo BioPharma Group Limited
BGS649	Obese hypogonadotropic hypogonadism	Removed	Transferred to Mereo BioPharma Group Limited
BKM120	Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor resistant, mTOR inhibitor naïve	Now disclosed as metastatic breast cancer, hormone receptor-positive, aromatase inhibitor resistant/mTOR naïve, 2nd line (+ fulvestrant)	
	Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor resistant	Now disclosed as metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor resistant, 3rd line (+ fulvestrant)	
BYL719	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 2nd line (+ fulvestrant)	Added	Entered Confirmatory Development
CNP520	Alzheimer's disease	Added	Entered Confirmatory Development
CTL019	Adult and pediatric acute lymphoblastic leukemia	Now disclosed as pediatric acute lymphoblastic leukemia	
Cosentyx (AIN457)	Non-radiographic axial spondyloarthritis	Added	Entered Confirmatory Development
	Psoriatic arthritis	Commercialized	
	Ankylosing spondylitis	Commercialized	
EMA401	Neuropathic Pain	Added	Acquired in acquisition of Spinifex Pharmaceuticals, Inc.

Entresto (LCZ696)	Chronic heart failure with reduced ejection fraction	Commercialized

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Project/Product	Potential indication/ Disease area	Change	Reason
	Post-acute myocardial infarction	Added	Entered Confirmatory Development
Jakavi	Polycythemia vera	Commercialized	
LBH589 (*Farydak*)	Relapsed or relapsed-and-refractory multiple myeloma	Commercialized	
LCQ908	Familial chylomicronemia syndrome	Removed	Development discontinued
LDE225 (*Odomzo*)	Advanced basal cell carcinoma	Commercialized	
LEE011	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women)	Now disclosed as hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 1st line (+ letrozole)	
	Hormone receptor-positive, HER2 negative advanced breast cancer (postmenopausal women), 1st/2nd line (+ fulvestrant)	Added	Entered Confirmatory Development
	Hormone receptor-positive, HER2 negative advanced breast cancer (premenopausal women)	Now disclosed as hormone receptor-positive, HER2 negative advanced breast cancer (premenopausal women), 1st line, (+ tamoxifen + goserelin or NSAI + goserelin)	
LGX818	Solid tumors	Removed	Divested to Array BioPharma Inc.
LIK066	Type 2 diabetes	Removed	Development discontinued
LJN452	Non-alcoholic steatohepatitis	Added	Entered Confirmatory Development

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Project/Product	Potential indication/ Disease area	Change	Reason
Lucentis	Choroidal neovascularization and macular edema secondary to conditions other than age-related macular degeneration, diabetic macular edema, retinal vein occlusion and pathologic myopia	Now disclosed as choroidal neovascularization secondary to conditions other than age-related macular degeneration and pathologic myopia	
MEK162	NRAS mutant melanoma	Removed	Rights returned to Array BioPharma Inc.
	Low-grade serous ovarian cancer	Removed	Rights returned to Array BioPharma Inc.
	Solid tumors	Removed	Rights returned to Array BioPharma Inc.
MEK162 and LGX818	BRAF mutant melanoma	Removed	MEK162 rights returned to Array BioPharma Inc. LGX818 divested to Array BioPharma Inc.
OAP030 (also known as *Fovista*/E10030)	Wet age-related macular degeneration	Now disclosed as neovascular age-related macular degeneration	
OMB157	Relapsing multiple sclerosis	Added	Acquired from GSK
PIM447	Hematologic tumors	Added	Entered Confirmatory Development
Promacta/Revolade	Pediatric immune thrombocytopenia	Added	Acquired from GSK
QGE031	Asthma	Removed	Development discontinued
	Chronic spontaneous urticaria/ Inducible urticaria	Added	Entered Confirmatory Development
QMF149	Asthma	Added	Entered Confirmatory Development
QVM149	Asthma	Added	Entered Confirmatory Development

Seebri (NVA237)	Chronic obstructive pulmonary disease	Commercialized

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Project/Product	Potential indication/ Disease area	Change	Reason
Tafinlar + Mekinist	BRAF V600+ non-small-cell lung cancer	Added	Acquired from GSK
	BRAF V600+ melanoma (adjuvant)	Added	Acquired from GSK
	BRAF V600+ colorectal cancer	Added	Acquired from GSK
Tekturna	Reduction of cardiovascular death/ hospitalizations in chronic heart failure patients	Removed	Development discontinued
*Ultibro (*QVA149*)*	Chronic obstructive pulmonary disease	Commercialized	
Votrient	Renal cell carcinoma (adjuvant)	Added	Acquired from GSK
VAY736	Primary Sjoegren's syndrome	Added	Entered Confirmatory Development
Zykadia (LDK378)	ALK + advanced non-small cell lung cancer (brain metastases)	Added	Entered Confirmatory Development
	ALK + advanced non-small cell lung cancer (post chemotherapy and post crizotinib)	Commercialized	
	ALK + advanced non-small cell lung cancer (chemotherapy naïve, crizotinib naïve)	Now disclosed as ALK + advanced non-small cell lung cancer (first line, treatment naïve)	

Principal Markets

The Pharmaceuticals Division sells products in approximately 155 countries worldwide. Net sales are generally concentrated in the US, Europe and Japan. However, sales from expanding "emerging growth

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markets" have become increasingly important to us. The following table sets forth the aggregate 2015 net sales of the Pharmaceuticals Division by region:

Pharmaceuticals	2015 Net sales to third parties	
	$ millions	%
Europe	10,139	33
United States	10,279	34
Asia, Africa, Australasia	7,224	24
Canada and Latin America	2,803	9
Total	**30,445**	**100**
Of which in Established Markets*	22,615	74
Of which in Emerging Growth Markets*	7,830	26

* 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 eleven pharmaceutical and four bulk chemical 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 "galenic" 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 and in various other locations. Operational responsibility for biologics manufacturing at our facilities in Huningue, France and Singapore, and at our Sandoz Division facilities in Kundl and Schaftenau, Austria, and Menges, Slovenia, has been brought together within our Pharmaceuticals Division. In addition, we own and operate a Good Manufacturing Practices quality cell processing site in Morris Plains, New Jersey. In 2015, we announced the closing of our site in Resende, Brazil and the downsizing of our site in Ringaskiddy, Ireland, and finalized the divestment of our manufacturing site in Taboão de 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 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.

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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 nearly 2,000 field force representatives in the US, and an additional nearly 20,000 in the rest of the world, as of December 31, 2015, 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 continue to see increasing influence of customer groups beyond prescribers, and Novartis is responding by adapting our business practices to engage appropriately with such constituencies.

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. The growing number of so-called "specialty" drugs in our portfolio has resulted in increased engagement with specialty pharmacies. In the US, specialty pharmacies continue to grow as a distribution channel for specialty products, with an increasing number of health plans mandating use of specialty pharmacies to monitor specialty drug utilization and costs.

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 seeks to assist the patient, delivering innovative solutions to drive education, access, and improved patient care.

As a result of continuing changes in healthcare economics and an aging population, the US Centers for Medicare & Medicaid Services (CMS) is now the largest single payor for healthcare services in the US. In addition, both commercial and government sponsored managed care organizations continue to be one of the largest groups of payors for healthcare services in the US. In other territories, national health services are often the only significant payor for healthcare services. In an effort to control prescription drug costs, almost all managed care organizations and national health services use formularies that list specific drugs that may be reimbursed, and/or the level of reimbursement for each drug. Managed care organizations and national health services also increasingly utilize various cost-benefit analyses to determine whether or not newly-approved drugs will be added to a formulary and/or the level of reimbursement for that drug, and whether or not to continue to reimburse existing drugs. We have dedicated teams that actively seek 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

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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.

There is ongoing consolidation in the pharmaceutical industry. At the same time, new entrants are looking to use their expertise to establish or expand their presence in healthcare, including technology companies hoping to benefit as data and data management become increasingly important in our industry.

Research and Development

We are a leader in the pharmaceuticals industry in terms of research and development, including the level of our investment. In 2015, our Pharmaceuticals Division expensed $7.2 billion (on a core basis $7.1 billion) in research and development, which amounted to 24% of the division's net sales. For additional information about research and development expenditures by our Pharmaceuticals Division over the last three years, please see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Results of Operations Research and development."

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.

Research program

Our Research program is conducted by the Novartis Institutes for BioMedical Research (NIBR), which is responsible for the discovery of new medicines. We established NIBR in 2003. 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.

At NIBR's headquarters in Cambridge, Massachusetts, and at sites in Switzerland, Singapore, China and three other US locations, more than 6,000 scientists, physicians and business professionals contribute to research into disease areas such as cardiovascular and metabolism disease, neuroscience, oncology, muscle disorders, ophthalmology, autoimmune 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, the Friedrich Miescher Institute, and the Genomics

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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.

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. Following proof-of-concept, our Pharmaceuticals Division conducts confirmatory trials on the drug candidates.

In 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 2014, as part of its alliance with Novartis, Penn announced plans for the construction of the Center for Advanced Cellular Therapeutics (CACT) on the Perelman School of Medicine campus in Philadelphia, Pennsylvania. 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 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.

In January 2015, we announced collaboration and licensing agreements with Intellia Therapeutics for the discovery and development of new medicines using CRISPR genome editing technology and Caribou Biosciences for the development of drug discovery tools. CRISPR, an acronym that stands for clustered regularly interspaced short palindromic repeats, is an approach that allows scientists to easily and precisely edit the genes of targeted cells. In a short period of time it has proven to be a powerful tool for creating very specific models of disease for use in drug discovery and has potential for use as a therapeutic modality for treating disease at the genetic level by deleting, repairing or replacing the genes that cause disease.

In March 2015, we entered into a collaboration with Aduro Biotech focused on the discovery and development of next generation cancer immunotherapies targeting the STING signaling pathway. STING is a signaling pathway that when activated is known to initiate broad innate and adaptive immune responses in tumors. Aduro's novel small molecule cyclic dinucleotides (CDNs) have proven to generate an immune response in preclinical models that specifically attacks tumor cells. In addition, we launched a new research group dedicated to immuno-oncology.

In September 2015, we announced that NIBR's President Dr. Mark Fishman will retire when he reaches his contractual retirement age in March 2016. Dr. James E. Bradner, a physician-scientist from Dana Farber Cancer Institute and Harvard Medical School has been named Dr. Fishman's successor.

In January 2016, we announced a collaboration and licensing agreement with Surface Oncology, which gives Novartis access to four pre-clinical programs in immuno-oncology.

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 subjects. The

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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

In 2014, Novartis Pharmaceuticals created a franchise focused on the development and commercialization of Cell and Gene Therapies. The Cell and Gene Therapies franchise 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 developing a portfolio of new treatments that replace, repopulate and/or reprogram cells, and potentially selectively regulate the immune system. The franchise will initially focus on novel cell therapies and cell-based gene therapies including: Chimeric Antigen Receptor T-Cell technology 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.

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.

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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. 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. In all major countries, products must be authorized or registered prior to marketing, and such authorization or registration must subsequently be maintained. In recent years, the registration process has required increased testing and documentation for the approval 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 safety, efficacy and quality 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 can vary significantly from country to country. It is possible that a drug can be registered and marketed in one country while the registration authority in another country may, prior to registration, request additional information from the pharmaceutical company or even reject the product. It is also possible that a drug may be approved for different indications in different countries.

The registration process generally takes between six months and several years, depending on the country, the quality of the data submitted, the efficiency of the registration authority's procedures and the nature of the product. Many countries provide for accelerated processing of registration applications for innovative products of particular therapeutic interest. In recent years, intensive efforts have been made among the US, the EU and Japan to harmonize registration requirements in order to achieve shorter

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development and registration times for medical products. However, the requirement in many countries to negotiate selling prices or reimbursement levels with government regulators and other payors can substantially extend the time until a product may finally be available to patients.

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 safety, efficacy and quality, 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 application 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.

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 safety, efficacy and quality, 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

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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 case 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 a European 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. For some medications, post approval studies (Phase IV) may be required to complement available data with additional data to evaluate long term effects (called a Post Approval Safety Study, or PASS) or to gather additional efficacy data (called a Post Approval Efficacy Study, or PAES).

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 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

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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), the recurring focus on deficit reduction, and public pressure on elected officials based on recent price increases by certain pharmaceutical manufacturers, there is a significant likelihood 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 (IPAB), 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. The Medicare Trustees' Report from July 2015 predicted that the projected 5-year average growth in per capita Medicare program spending could exceed a specified target level as early as 2017. If the Chief Actuary for CMS determines that the projected 5-year average growth rate exceeds the target, the IPAB would then develop savings proposals in 2018 based on a savings target set by the Chief Actuary, to be implemented in 2019. There is also a possibility that government officials will continue to search for additional 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 strict analyses are applied when evaluating the entry of new products, and, as a result, payors are more frequently limiting access to innovative medicines based on these strict cost-benefit analyses. In addition, prices for marketed products are referenced within Member States and across Member State borders, including new EU Member States, further impacting individual EU Member State pricing.

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. In addition, the MHLW has proposed extraordinary price cuts in 2016 for certain products the sales of which have increased substantially more than official forecasts.

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Rest of World. Many other countries around the world are also taking steps to control prescription drug prices. As an example, China, one of our most important emerging growth markets, organized tendering in every province, with requested drug price reductions of up to 20% in 2015. Drug prices in China may further decline due to a stated national policy of reducing healthcare costs, including recent strategic initiatives implemented at the province level specifically designed to reduce drug prices. China has also been monitoring drug pricing for irregularities in the market. Although the ultimate impact of this monitoring on the regulatory and pricing framework is not yet clear, China is developing a new pricing framework in which price reductions remain a consistent national priority.

Regulations favoring generics and biosimilars

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. In addition, the US, EU and other jurisdictions are increasingly developing laws and regulations encouraging the development of biosimilar versions of biologic drugs, which can also be expected to have an impact on pricing.

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 will likely 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. Even though we may own, co-own or in-license patents protecting our products,

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and conduct pre-launch freedom-to-operate analyses, a third party may nevertheless claim that one of our products infringes a third party patent for which we do not have a license.

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. Data exclusivity and other regulatory exclusivity periods generally run from the date a product is approved, and so their expiration dates cannot be known with certainty until the product approval date is known.

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.

Patents, patent term extensions and marketing exclusivities can be challenged through various proceedings that depend on the country. For example, patents in the US can be challenged in the United States Patent and Trademark Office (USPTO) through various proceedings, including Inter Partes Review (IPR) proceedings. They may also be challenged through patent infringement litigation under the Hatch-Waxman Act. See generally, " Sandoz Intellectual Property" In the EU, EU patents may be challenged through oppositions in the European Patent Office (EPO) or national patents may be challenged in national courts or national patent offices. In Japan, patents may be challenged in the Japanese patent office and in national courts.

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 patent term adjustments for USPTO delay. A US pharmaceutical patent which claims a product, method of treatment using a product, or method of manufacturing a product, may also be eligible for a patent term extension 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. Regulatory data protection or 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.

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A new small-molecule active pharmaceutical ingredient shall have 5 years of regulatory 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 pediatric 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 EPO or in a particular country in Europe. The EPO system permits a single application to be granted for the EU, plus other non-EU countries, such as Switzerland and Turkey. When the EPO grants a patent, it is then validated in the countries that the patent owner designates. A patent granted by the EPO or a European country office will expire no later than 21 years from the earliest patent application on which the patent is based. Pharmaceutical patents can also be granted a further period of exclusivity under the Supplementary Protection Certificate (SPC) system. SPCs are designed to compensate the owner of the patent for the time it took to receive marketing authorization by the European Health Authorities. An SPC may be granted to provide, in combination with the patent, up to 15 years of exclusivity from the date of the first European marketing authorization. However, an 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 2005, therefore some medicines remain covered by the previous system in which EU member states provided either 6 or 10 years of data exclusivity.

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The EU also has an orphan drug exclusivity 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. A patent term extension can be granted for 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. Japan also has an 8-year regulatory data protection system called a "re-examination period" and a 10-year orphan drug exclusivity system.

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 certain additional details regarding intellectual property protection for selected Pharmaceuticals Division products and compounds in development. Administrative proceedings or litigation to obtain intellectual property, to enforce intellectual property or to resolve challenges to intellectual property are uncertain and unpredictable. In some circumstances a competitor may be able to market a generic version of one of our products despite the existence of our intellectual property by, for example, designing around our intellectual property or marketing the generic product for non-protected indications. Despite data exclusivity protections, a competitor could opt to incur the costs of conducting its own clinical trials and preparing its own regulatory application, and avoid our data exclusivity protection altogether. There is also a risk that some countries 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. As a result, there can be no assurance that our intellectual property will protect our products or that we will be able to avoid adverse effects from the loss of intellectual property protection in the future.

For each selected product or compound in development, we identify certain issued, unexpired patents by general subject matter and, in parentheses, years of expiry in, if relevant, the US, EU and Japan that are owned, co-owned or exclusively in-licensed by Novartis and that relate to one or more forms of the product or methods of use. Novartis may own or control additional patents relating to compound forms, formulations, processes, synthesis, purification and detection. For additional information regarding commercial arrangements with respect to these products, see " Key Marketed Products." Identification of an EU patent refers to national patents in EU countries and/or to the national patents that have been derived from a patent granted by the EPO. We identify unexpired regulatory data protection periods and, in parentheses, years of expiry for selected products and compounds in development if the relevant marketing authorizations have been authorized or granted. The term "RDP" refers to regulatory data protection, regulatory data exclusivity (which in the EU refers to the protections under "8+2+1" regulatory data exclusivity), and to data re-examination protection systems. We also identify certain unexpired patent term extensions, SPCs and marketing exclusivities and, in parentheses, years of expiry if they are granted; their subject matter scope may be limited, and is not specified. We designate them as "pending" if they have been applied for but not granted and years of expiry are estimable. Such pending applications may or may not ultimately be granted. In the case of the EU, grant or authorization of a patent term extension, marketing exclusivity or data protection means grant or authorization in at least

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one country and possibly pending in others. Marketing exclusivities and patent term extensions include orphan drug exclusivity (ODE), pediatric exclusivity (PE), patent term extension (PTE) and SPC. For each selected product and compound in development, we indicate whether there is current generic competition for one or more product versions or approved indications in each of the major markets for which intellectual property is identified. We also identify ongoing challenges to the disclosed intellectual property that have not been finally resolved without indicating the likelihood of success in each individual case. Resolution of such challenges may include agreements under which Novartis grants licenses permitting marketing of generic versions of our products before expiration of the relevant intellectual property. We disclose certain material terms of certain settlement agreements relating to certain selected products and compounds in development where they could have a material adverse effect on our business. In other cases, certain settlement agreements may contain confidentiality obligations restricting what may be disclosed.

Oncology

Gleevec/Glivec. US: Patent on polymorphic compound form (2019), PE (2019); patent on GIST method of use (2021), PE (2022); patent on tablet formulation (2018). EU: Patent on compound (2013), SPC (2016), PE (2016); patent on polymorphic compound form (2018); patent on GIST method of use (2021); patent on tablet formulation (2023). Japan: Patent on polymorphic compound form (2019); patent on GIST method of use (2021); patent on tablet formulation (2023).

There is currently no generic competition in the US. There is generic competition in Japan and some EU countries. In the US, Novartis has resolved patent litigation with certain generic manufacturers. Novartis has licensed a subsidiary of Sun Pharmaceutical Industries to market a generic version of *Gleevec* in the US as of February 1, 2016. Additional generic manufacturers have filed ANDAs challenging the US polymorphic compound form patent; the earliest automatic 30-month stay preventing FDA approval will expire in December 2016. Novartis is taking steps in some EU countries to enforce the EU compound patent, the EU polymorphic compound form patent and the EU GIST method of use patent against generic manufacturers. The EU compound patent PE and the EU GIST method of use patent are being challenged in the patent offices and courts of several EU countries.

Afinitor/Votubia and *Afinitor Disperz/Votubia* dispersible tablets and *Zortress/Certican*.

Afinitor/Votubia and *Afinitor Disperz/Votubia* dispersible tablets: US: Patent on compound (2014), PTE (2019), PE (2020); patent on tablet formulation (2016), PE (2017); patent on dispersible tablet formulation (2022), PE (2023); patents on antioxidant (2019), PE (2020); patent on TSC/SEGA use (2022), PE 2022); patent on breast cancer use (2022), PE (2022); patent on renal cell carcinoma use (2025), PE (2026); patent on pancreatic neuroendocrine tumor use (2028). EU: Patent on compound (2013), SPC (2018); patent on tablet formulation (2016); patent on dispersible tablet formulation (2022); patent on antioxidant (2019); patent on breast cancer use (2022); patent on pancreatic neuroendocrine tumor use (2026); ODE (*Votubia*) (2021). Japan: Patent on compound (2013), PTE (2018); patent on tablet formulation (2016); patent on dispersible tablet formulation (2022); patent on antioxidant (2019); patent on breast cancer use (2022); patent on pancreatic neuroendocrine tumor use (2026); patent on renal cell carcinoma use (2022); ODE (tuberous sclerosis) (2022); RDP (2018).

There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging several patents; the earliest automatic 30-month stay preventing FDA approval will expire in October 2017. The US compound patent and antioxidant patents are being challenged in IPR proceedings in the USPTO.

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Zortress/Certican: US: Patent on compound (2014), PTE (2019), PE (2020); patent on tablet formulation (2016), PE (2017); patent on dispersible tablet formulation (2022), PE (2023); two patents on antioxidant (2019, 2019); patents on methods of use (2017, PE (2018)). EU: Patent on compound (2013), SPC (2018); patent on tablet formulation (2016); patent on dispersible tablet formulation (2022); patent on antioxidant (2019). Japan: Patent on compound (2013), PTE (2018); patent on tablet formulation (2016); patent on dispersible tablet formulation (2022); patent on antioxidant (2019).

There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging several patents; the earliest automatic 30-month stay preventing FDA approval will expire in March 2017. The US compound patent and a method of use patent are being challenged in IPR proceedings in the USPTO.

Tasigna. US: Patent on compound (2023); patents on salt forms (2026, 2027, 2028); patent on polymorph compound form (2026). EU: Patent on compound (2023); patent on salt form (2026); patent on polymorph compound form (2026); ODE (2017). Japan: Patent on compound (2023), PTE (2024); patent on salt form (2026); patent on polymorph compound form (2026); RDP (2017). There is currently no generic competition in the US, EU or Japan. The EU salt form patent and polymorph compound form patent are being opposed in the EPO.

Sandostatin. Sandostatin SC: There is no patent protection in the US, EU or Japan. There is generic competition in the US, EU and Japan. *Sandostatin LAR*: US: Patent on microparticles (2017). There is no patent protection in the EU or Japan. There is currently no generic competition in the US, EU or Japan.

Exjade and *Jadenu. Exjade*: US: Patent on compound (2019); patent on method of use (2017). EU: Patent on compound (2017), SPC (2021); patent on tablet formulation (2023); ODE (2016). Japan: Patent on compound (2017), SPC (2021); RDP (2016). There is currently no generic competition in the US, EU or Japan. In the US, Novartis has resolved patent litigation with generic manufacturers relating to *Exjade*.

Jadenu: The compound patents in the US, EU and Japan and the US method of use patent identified for *Exjade* also protect *Jadenu*. There is currently no generic competition in the US, EU or Japan. In the US, a generic manufacturer has filed an ANDA challenging the US compound patent; the earliest automatic 30-month stay preventing FDA approval will expire in May 2018.

Votrient. US: Patent on compound (2021), PTE (2023), ODE (2019). EU: Patent on compound (2021), SPC (2025); RDP (2020). Japan: patent on compound (2021), PTE (2025); RDP (2020). There is currently no generic competition in the US, EU or Japan.

Tafinlar and *Mekinist. Tafinlar*: US: Patent on compound (2030); RDP (2018); ODE (2020). EU: RDP (2023). Japan: Patent on compound (2029). There is currently no generic competition in the US, EU or Japan. *Mekinist*: US: Patent on compound (2025), pending PTE (2027); patent on method of use (2025); patent on formulation (2032); RDP (2018); ODE (2020). EU: Patent on compound and method of use (2025), SPC (2029); RDP (2025). Japan: Patent on compound (2025); patent on method of use (2025); patent on formulation (2031). There is currently no generic competition in the US, EU or Japan. Use of *Mekinist* with *Taflinar* or *Taflinar* with *Mekinist*: US: Patent on use of *Tafinlar* and *Mekinist* (2030); RDP (2017); ODE 2021. EU: RDP (2025). Japan: Patent on use of *Tafinlar* and *Mekinist* (2030). There is currently no generic competition in the US, EU or Japan.

Jakavi. EU: Patent on compound (2026), SPC (2027); patent on salt (2028); RDP (2023). Japan: Patent on compound (2026), PTE (2028), pending PTE (2030); patent on salt (2028), PTE (2028), pending PTE (2030); patent on compositions for medical uses (2026), pending PTE (2027); RDP

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(2022). There is currently no generic competition in the EU or Japan. The EU salt patent is being opposed in the EPO.

Promacta/Revolade. US: Patent on compound (2021), PTE (2022), PE (2023); patent on salt form (2025); patent on formulation (2027). EU: Patent on compound (2021), SPC (2025); patent on salt form (2023); patent on formulation (2027). Japan: Patent on compound (2021), PE (2025); patent on salt form (2023); patent on formulation (2027). There is currently no generic competition in the US, EU or Japan.

Farydak. US: Patent on compound (2021), pending PTE (2026); patent on method of use (2026); patent on crystalline salt (2028); RDP (2020). EU: Patent on compound (2021), pending SPC (2026); patent on method of use (2026); RDP (2025). Japan: Patent on compound (2021), pending PTE (2026); patent on method of use (2026); RDP (2023). There is currently no generic competition in the US, EU or Japan.

Odomzo. US: Patent on compound (2029), pending PTE (2029); patent on salt form (2029); RDP (2020). EU: Patent on compound (2027), pending SPC (2030); patent on salt form (2029); RDP (2025). Japan: Patent on compound (2027); patent on salt form (2029). There is currently no generic competition in the US, EU or Japan.

Arzerra. US: Patent on compound (2031); RDP (2023). EU: Patent on compound (2023), SPC (2025); RDP (2021). Japan: Patent on compound (2023), PTE (2025); patent on formulation (2028); RDP (2019). There is currently no generic competition in the US, EU or Japan.

Cardio-Metabolic

Galvus and *Eucreas*. EU: Patent on compound (2019), SPC (2022); patent on combination (2021), SPC (2022); patent on *Eucreas* formulation (2026); RDP (2017). Japan: Patent on compound (2019), PTE (2024), pending PTE (2024); patent on combination (2021); patent on *Galvus* formulation (2025), PTE (2025); patent on *Eucreas* formulation (2026), pending PTE (2028); *Galvus* RDP (2018); *Eucreas* RDP (2019). *Galvus/Eucreas* is not marketed in the US. There is currently no generic competition in the EU or Japan. The EU *Eucreas* formulation patent is being opposed in the EPO.

Entresto. US: Patents on combination (2023); patent on complex (2027); RDP (2020). EU: Patent on combination (2023); patent on complex (2026); patent on formulation (2028); RDP (2025). Japan: Patent on combination (2023); patent on complex (2026); patent on formulation (2028). There is currently no generic competition in the US, EU or Japan. The EU complex patent and the EU formulation patent are being opposed in the EPO.

Immunology and Dermatology

Neoral. There is no patent protection for *Neoral* in the US, EU or Japan. There is generic competition in the US, EU and Japan.

Myfortic. US: Patent on formulation (2017), PTE (2018); patent on particle size (2024). EU: Patent on formulation (2017), SPC (2017); patent on formulation (2022); patent on particle size (2024). There is generic competition in the US. There is currently no generic competition in the EU. In the EU, Novartis has resolved patent litigation with a generic manufacturer. The EU formulation patent and particle size patent are being opposed in the EPO.

Xolair. US: Patent on compound (2018); patent on lyophilized formulation (2016), PTE (2017); patents on syringe formulation (2021, 2024). EU: Patent on compound (2012), SPC (2017); patent on lyophilized formulation (2016); patents on syringe formulation (2021, 2024). Japan: Patent on compound (2012), PTE (2017); patent on lyophilized formulation (2016); patents on syringe formulation (2021, 2024); RDP (2017). There is currently no generic competition in the US, EU

or

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Japan. The EU syringe formulation patent and lyophilized formulation patent are being opposed in the EPO.

Cosentyx. US: Patent on compound (2027), pending PTE (2029); RDP (2027). EU: Patent on compound (2025), pending SPC (2030), pending PE (2030); RDP (2026). Japan: Patent on compound (2025), PTE (2029); patent on method of use (2031), PTE (2032); RDP (2022). There is currently no generic competition in the US, EU, or Japan.

Retina

Lucentis. EU: Patent on compound (2018), SPC (2022); patent on method of use (2016). Japan: Patent on compound (2018), PTE (AMD indication) (2019), PTE (other indications) (2023). There is currently no generic competition in the EU or Japan.

Neuroscience

Gilenya. US: Patent on compound (2014), PTE (2019); patent on formulation (2026); patent on dose (2027). EU: Patent on compound (2013), SPC (2018); RDP (2021); patent on formulation (2024), SPC (2026). There is currently no generic competition in the US or EU. In the US, generic manufacturers have filed ANDAs challenging the US compound patent and formulation patent; the earliest automatic 30-month stays preventing FDA approval will expire in March 2018. Generic manufacturers have filed ANDAs challenging the US dose patent. The US formulation patent is being challenged in an IPR proceeding in the USPTO.

Exelon/Exelon Patch. Exelon: There is no patent protection for *Exelon* capsules in the US, EU or Japan. There is generic competition in the US, EU and Japan. *Exelon Patch*: US: Patents on formulations (2019). EU: Patent on formulation (2019); patent on transdermal dosage regime (2026). Japan: Patent on formulation (2019); RDP (2019). There is generic competition in the US and in most EU countries. There is currently no generic competition in Japan. We are taking steps in several countries to enforce our EU transdermal dosage regime patent against generic competitors. The EU transdermal dosage regime patent is being opposed in the EPO and several national patents are being challenged in national courts. In the US, generic manufacturers have filed ANDAs challenging the US formulation patents; the earliest automatic 30-month stays preventing FDA approval expires in 2017. The US formulation patents are being challenged in an IPR proceeding in the USPTO.

Established Medicines

Diovan and *Co-Diovan/Diovan HCT. Diovan*: US: Patent on formulation (2017), PE (2017). There is generic competition in the US, EU and Japan. *Co-Diovan/Diovan HCT*: US: Patent on formulation (2017), PE (2017). Japan: Patent on compound (2011), PTE for *Co-Diovan* (2016); patent on formulation (2017). In Japan, Novartis has resolved patent litigation with a generic manufacturer. There is generic competition in the US and EU. There is currently no generic competition in Japan.

Exforge and *Exforge HCT. Exforge*: US: Patent on *Exforge* combination (2019). EU: Patent on *Exforge* combination/*Exforge HCT* combination (2019); RDP (2017). There is generic competition in the US and Japan. There is currently no generic competition in the EU. The EU *Exforge* combination/*Exforge HCT* combination patent is being challenged in the patent offices of some EU countries. We are taking steps to enforce the EU *Exforge* combination/*Exforge HCT* combination patent against generic manufacturers seeking to market *Exforge*. *Exforge HCT*: US: Patent on *Exforge HCT* combination (2023). EU: patent on *Exforge* combination/*Exforge HCT* combination (2019); RDP (2019). Japan: Patent on *Exforge HCT* combination (2023). There is generic

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competition in the US. There is currently no generic competition in the EU. *Exforge HCT* is not currently marketed in Japan.

Voltaren/Cataflam. There is no patent protection in the US, EU or Japan. There is generic competition in the US, EU and Japan.

Ritalin LA/Focalin XR. US: Patent on drug-delivery formulation (2019). EU: Patent on dose (2018); patent on drug-delivery formulations (2019). Japan: Patent on dose (2018); patent on drug-delivery formulation (2019). There is generic competition in the US for *Ritalin LA* and *Focalin XR*. There is currently no generic competition in the EU or Japan. The EU formulation patent is being opposed in the EPO.

Compounds in Development

We provide the following information regarding our compounds in Phase III clinical development, if any, that have been submitted for registration to the FDA or the EMA: As of the date of this 20-F, the only compounds that we have in Phase III clinical development that have been submitted for registration to the FDA or the EMA are compounds that have previously been approved by FDA or EMA, and have been submitted for the approval of one or more additional indications. See above for intellectual property information regarding our selected Pharmaceuticals Division products.

ALCON

Our Alcon Division is a leader in the research, development, manufacturing and marketing of eye care products worldwide, and its products are available in more than 180 markets. In 2015, the Alcon Division had consolidated net sales of $9.8 billion representing 20% of total Group net sales.

Alcon offers an extensive breadth of products serving the full lifecycle of patient needs across eye diseases, vision conditions and refractive errors. To meet the needs of patients, ophthalmologists, surgeons, optometrists, opticians and physician specialists, Alcon operates with three franchises: Surgical, Ophthalmic Pharmaceuticals and Vision Care. Each franchise operates with specialized sales forces and marketing support.

To accelerate growth, we are taking concerted action on two fronts. For the Surgical and Vision Care franchises, we have identified key actions as part of a growth plan. They include steps to optimize innovation in intraocular lenses (IOLs) for cataract surgery, prioritizing and investing in the development of promising new products, and improving the effectiveness of our sales force.

In addition, we plan to strengthen our ophthalmic medicines business by transferring Ophthalmic Pharmaceuticals products from Alcon to our Pharmaceuticals Division, combining expertise in pharmaceuticals development and marketing with the strong Alcon brand.

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 Verily (formerly Google Life Sciences) 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 IOLs. Alcon has integrated the *ORA System* into its existing *Cataract Refractive Suite* by Alcon.

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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 *Contoura* vision, the latest vision system in the *Wavelight* refractive suite portfolio for refractive procedures and LASIK treatments, the *Constellation* vision system for retinal operations, and the *Infiniti* vision system to perform cataract surgeries, which is the phacoemulsification platform introduced prior to the *Centurion* vision system. Alcon also offers the *AcrySof* family of intraocular lenses (IOLs) to treat cataracts, including the *AcrySof IQ*, *AcrySof IQ PanOptix*, *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; *Azopt*, *Azarga*, *Travatan Z* 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; *Pazeo* and *Pataday* ophthalmic solutions 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.

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* monthly contact lens product line includes *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 received a number of approvals and launched a number of products in 2015, including:

AcrySof IQ aspheric intraocular lens with *UltraSert* Pre-loaded Delivery System was approved in the US and EU to provide a single-use system for cataract surgery.

AcrySof IQ PanOptix trifocal intraocular lens was launched in the EU for patients seeking presbyopia-correction during cataract surgery.

AcrySof IQ ReSTOR multifocal +2.5D intraocular lens was approved in the US for patients wanting near, intermediate and distance vision correction during cataract surgery.

Air Optix Colors contact lenses: silicone hydrogel, color cosmetic monthly contact lenses were launched in Japan.

Air Optix Colors contact lenses in plus powers were launched in the US for patients with hyperopia.

Air Optix with *HydraGlyde* contact lenses received approval in the EU for longer-lasting surface wettability.

Clear Care Plus/AOSept Plus with *HydraGlyde* was launched in the US and EU to provide hydrogen peroxide-based cleaning and disinfecting for contact lenses.

Contoura vision topography guided, refractive surgical system was launched in the US for patients seeking myopic and astigmatic vision correction.

Dailies Total1 contact lenses with plus powers were launched in the US and EU for patients with hyperopia seeking a daily disposable lens.

LuxOr ceiling-mounted ophthalmic microscope system was approved in the US for enhanced visualization during cataract surgery.

ORA System with *VerifEye+* was launched in the US and EU for enhanced pre-operative planning during cataract surgery.

Pazeo Solution (olopatadine hydrochloride) for 24-hour ocular allergy itch relief was approved and launched in the US.

Systane Hydration lubricant eye drops in unit-dose and multi-dose were launched in the EU for the palliative treatment of dry eye.

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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 PanOptix, 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 *UltraSert* pre-loaded delivery system for intraocular lenses that correct cataracts *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 *Contoura* vision for LASIK vision correction in patients with myopia and astigmatism *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.

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Ophthalmic Pharmaceuticals

Glaucoma	*Simbrinza* suspension to lower intraocular pressure without a beta blocker
	Izba, Travatan and *Travatan Z* ophthalmic solutions to lower intraocular pressure
	Azopt ophthalmic suspension to lower intraocular pressure
	DuoTrav ophthalmic solution to lower intraocular pressure (outside US markets)
	Azarga/Azorga ophthalmic suspension to lower intraocular pressure (outside US markets)
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 Hydration 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
Allergy	*Pazeo, 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

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

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

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 Plus* cleaning and disinfecting solution (*AOSept Plus* outside of North America)

Selected Development Projects

Surgical

Project/Product[1]	Mechanism of action	Potential indication	Planned submission date/Current Phase
AcrySof IQ ReSTOR Toric 2.5D IOL	Multifocal, aspheric and cylinder correcting intraocular lens	Cataractous lens replacement with or without presbyopia, and with astigmatism	2016 US/Advanced development
AcrySof IQ ReSTOR Toric 3.0D IOL	Multifocal, aspheric and cylinder correcting intraocular lens	Cataractous lens replacement with or without presbyopia, and with astigmatism	US/Submitted[2]
AcrySof IQ Aspheric IOL with UltraSert	Pre-loaded intraocular lens delivery device	Cataractous lens replacement	Japan/Submitted[3]

(1) *AcrySof IQ ReSTOR Toric 3.0D* diopter range expansion IOL was terminated in July 2015, as clinical data did not support submissions in the US or Japan.

(2) Submitted to the FDA in 2014. Additional information regarding clinical data has been requested by the FDA.

(3) Submission pending acceptance by regulatory authority.

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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
Jetrea Ready-Diluted Injection (ocriplasmin)	Alpha-2 antiplasmin reducer	Retina (vitreomacular traction)	Intravitreal injection	2017 Japan/III
Ilevro (nepafenac 0.3%)	Anti-inflammation	Postsurgical macular edema in patients with diabetes	Topical	EU Submitted 2018 US/III
RTH258 (brolucizumab)	Anti-VEGF single-chain antibody fragment	Wet age-related macular degeneration	Intravitreal injection	≥ 2018/III

Submission pending acceptance by regulatory authority.

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	2017 Japan/Advanced development

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 2015 net sales of the Alcon Division by region:

Alcon Division	2015 Net Sales to third parties	
	$ millions	%
Europe	2,408	25
United States	4,275	44
Asia, Africa, Australasia	2,154	22
Canada and Latin America	975	9
Total	**9,812**	**100**
Of which in Established Markets*	7,423	76
Of which in Emerging Growth Markets*	2,389	24

* 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.

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Research and Development

In 2015, 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 $0.9 billion (on a core basis $0.9 billion) and $1.0 billion (on a core basis $0.9 billion) in research and development in 2014 and 2013, respectively. Core results exclude impairments, amortization and certain exceptional items. For additional information, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis Core Results."

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 errors. 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.

In addition, the Novartis Institutes for BioMedical Research (NIBR) is the Novartis global pharmaceutical research organization that works to discover innovative medicines to 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 contact 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 Verily (formerly Google Life Sciences), and has licensed its smart lens technology for ocular medical uses, including the potential to provide an accommodative contact lens/intraocular lens for patients living with presbyopia and to monitor glucose levels in diabetic patients. The Ophthalmic Pharmaceuticals franchise is focused on the development of products for the treatment of retinal diseases, glaucoma (intraocular pressure lowering) and dry eye.

Production

We manufacture our Alcon Division's pharmaceutical products at six facilities in the United States, Belgium, Spain, Brazil and Singapore. Our Alcon Division's surgical equipment and other surgical medical devices are manufactured at nine 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 some of 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

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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.

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.

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.

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Regulation

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

Our Surgical and Vision Care products are regulated as medical devices in the US and the EU. These jurisdictions each have risk-based classification systems that determine the type of information 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.

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, its use 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 typically challenge infringements of our intellectual property. We also defend challenges, often by generic manufacturers, to the validity of our intellectual property. However, because the outcome of intellectual property litigation is uncertain and unpredictable, there can be no assurance that we will be able to successfully protect our intellectual property rights in all cases. See generally " Pharmaceuticals Intellectual Property."

We take reasonable steps to ensure that our products do not infringe valid intellectual property rights held by others. Nevertheless, third parties may assert patent and other intellectual property rights against our products. As a result, we can become involved in significant intellectual property litigation regarding our products. If we are unsuccessful in defending these suits, we could be subject to injunctions preventing us from selling our products and to damages, which may be substantial. Litigation or administrative proceedings challenging the validity of our intellectual property is similarly unpredictable. If we are

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unsuccessful in such proceedings, we may face loss of exclusivity and increased competition in the affected territories.

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 generic pharmaceuticals and biosimilars and sells products in products in more than 160 countries. In 2015, the Sandoz Division achieved consolidated net sales of $9.2 billion, representing 18% 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 areas of dermatology, respiratory and ophthalmics, as well as cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies. Finished dosage form anti-infectives sold to third parties are also a part of Retail Generics.

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 and provides biotechnology manufacturing services to other companies, and in Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

Sandoz develops, produces and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients. Nearly half of the Sandoz portfolio, in terms of sales, is in differentiated products products that are scientifically more difficult to develop and manufacture than standard generics. Examples of differentiated products in the Sandoz portfolio are the multiple sclerosis treatment *Glatopa* (glatiramer acetate injection), the cardiovascular polypill *Sincronium* (acetylsalicylic acid, atorvastatin and ramipril), and the pain medication fentanyl, which is difficult to manufacture because its delivery mechanism is a transdermal patch. Differentiated products also include biosimilars, which Sandoz began developing in 1996 and today sells in more than 60 countries. Sandoz is the market leader in biosimilars and all three of its biosimilars continue to demonstrate strong growth in their respective categories *Omnitrope*, a human growth hormone; *Binocrit,* an erythropoiesis-stimulating agent used to treat anemia; and filgrastim for neutropenia under the brand names *Zarzio* outside the US and *Zarxio* in the US. According to IMS Health, Sandoz holds the global #1 position in terms of sales in biosimilars and generic anti-infectives, as well as in ophthalmics and transplanattion medicines. In addition, Sandoz holds leading global positions in key therapeutic areas ranging from generic injectables, dermatology and respiratory to cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

Sandoz is focused on several key priorities, including investing in key markets and therapeutic areas, increasing the performance of its Development & Regulatory organization, optimizing its manufacturing network and maximizing opportunities in biosimilars.

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In 2015, key product launches in the US included *Glatopa*, the first generic version of Teva's Copaxone® 20mg (glatiramer acetate injection), the biosimilar *Zarxio* (filgrastim-sndz), and budesonide inhalation suspension (Astra Zeneca's Pulmicort Respules®), as well as authorized generic versions of the The Medicine Company's Angiomax® (bivalirudin) and our Pharmaceutical Division's *Exelon Patch* (rivastigmine patch).

In 2015, key product launches in various European countries included aripiprazole TAB (Atsuka's Abilify®), duloxetine (Eli Lilly's Cymbalta®) pregabalin HGC (Pfizer's Lyrica®) and valganciclovir FCT (Roche's Valcyte®). In addition, the global rollout of *AirFluSal Forspiro* continued with launches across Europe. As of December 31, 2015, *AirFluSal Forspiro* was marketed in 24 countries.

In 2015, 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.

New Products

Sandoz launched a number of important products in various countries in 2015, including:

Aripiprazole TAB (Atsuka's Abilify®)

Bivalirudin (authorized generic of The Medicine Company's Angiomax®)

Budesonide inhalation suspension (Astra Zeneca's Pulmicort Respules®)

Duloxetine (Eli Lilly's Cymbalta®)

Glatopa (Teva's Copaxone® 20mg; glatiramer acetate injection)

Rivastigmine patch (authorized generic of our Pharmaceutical Division's *Exelon Patch*)

Pregabalin HGC (Pfizer's Lyrica®)

Valganciclovir FCT (Roche's Valcyte®)

Zarxio (filgrastim-sndz)

Key Marketed Products

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

Retail Generics

Product	Originator Drug	Description
Acetylcysteine	Fluimucil®	Respiratory system
Amoxicillin/clavulanic acid	Augmentin®	Anti-infective
Atorvastatin	Lipitor®	Blood cholesterol reduction
Diclofenac	*Voltaren*	Analgesic

Fentanyl	Duragesic®	Analgesic
Levothyroxine Sodium	Synthroid®; Levoxyl®	Hypothyroidism treatment
Omeprazole	Prilosec®	Ulcer and heartburn treatment
Pantoprazole	Protonix®	Gastrointestinal
Potassium	Klor-Con®	Hypokalemia
Tacrolimus	Prograf®	Transplantation

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

Oncology Injectables

Product	Originator Drug	Description
Azacitidine	Vidaza®	Bone marrow cancer, leukemia
Bortezomib	Velcade®	Multiple myeloma, lymphoma
Cyclophosphamide	Endoxan®	Breast, ovarian and non-small cell lung cancer
Decitabine	Dacogen®	Bone marrow cancer, leukemia
Docetaxel	Taxotere®	Breast, ovarian and non-small cell lung cancer
Gemcitabine	Gemzar®	Bladder, pancreas, lung, ovarian, and breast cancer
Leuprorelin	Lupron®, Eligard®	Prostate cancer
Levoleucovorin Calcium	Fusilev®	Rescue after methotrexate high-dose therapy
Methotrexate	Folex®, Rheumatrex®	Arthritis; breast, lung, cervix and ovarian cancer, and others
Paclitaxel	Taxol®	Breast, lung and ovarian cancer, Kaposi sarcoma

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Biosimilars in Phase III Development and Registration

The following table describes Sandoz biosimilar projects that are in Phase III clinical trials (including filing preparation) and registration:

Project/product	Common name	Mechanism of action	Potential indication/ indications	Therapeutic areas	Route of administration	Current phase
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	US/EU: Registration
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	Nephrology	Subcutaneous	EU: Registration
LA-EP2006	pegfilgrastim	Pegylated granulocyte colony-stimulating factor	Chemotherapy-induced neutropenia and others (same as originator)	Oncology	Subcutaneous	US: Registration EU: III

* Planned submission for US.

** Filing in the EU for the addition of the subcutaneous (s.c.) route of administration for *Binocrit* nephrology indications.

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 2015 net sales of Sandoz by region:

Sandoz	2015 Net Sales to third parties	
	$ millions	%
Europe	3,925	43
United States	3,525	38
Asia, Africa, Australasia	1,150	13
Canada and Latin America	557	6
Total	**9,157**	**100**
Of which in Established Markets*	6,972	76

Of which in Emerging Growth Markets*	2,185	24

*

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.

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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 and EMA. 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 and Menges, Slovenia; Stryków, Poland. In 2015, we announced that we were exiting our manufacturing sites in Frankfurt and Gerlingen, Germany, as well as in Turbhe, India. We anticipate that these site exits will be completed by the end of 2016. Our global manufacturing strategy 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 biosimilars 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 strive to maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers, and competitive material sourcing can be assured. However, our ability to do so may at times be limited by regulatory or other requirements. We monitor market developments that could have an adverse effect on the supply of essential active pharmaceutical ingredients. All active pharmaceutical ingredients we purchase must comply with high quality standards.

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

In October 2015, we received a Warning Letter from the FDA with respect to our Kalwe and Turbhe, India manufacturing sites. The Warning Letter observations follow an FDA inspection at both sites in August 2014 and are related to deficiencies in current good manufacturing practice (cGMP) for finished pharmaceuticals. The Warning Letter did not contain any new issues in addition to the 483 observations issued following the August 2014 inspection. Sandoz plans to continue to collaborate with the FDA to resolve the Warning Letter observations.

In September 2015, the FDA confirmed that it closed out the May 2013 Warning Letter relating to our oncology injectables manufacturing facility in Unterach, Austria. That Warning Letter contained two observations which followed an FDA inspection at the site in October 2012, and were related to historical visual inspection practices for products manufactured at the site. A follow up inspection by the FDA in 2014 resulted in no observations.

In July 2014, the FDA confirmed that it had decided to close out the Warning Letter issued in November 2011 against three Sandoz 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,

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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.

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 and biosimilars 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.

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

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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, "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 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. 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 secure approval for a biosimilar under the US biosimilar pathway which was established as part of the Biologics Price Competition and Innovation Act (BPCIA).

The Sandoz Division explores alternative routes for the manufacture of known compounds and develops innovative dosage forms of well-established medicines. The Development and Registration staff employed by affiliates of the Sandoz Division 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 2015, 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

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expensed $0.8 billion (on a core basis $0.8 billion) and $0.8 billion (on a core basis $0.8 billion) in 2014 and 2013, respectively. Core results exclude impairments, amortization and certain exceptional items. For additional information, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis Core Results."

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 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. As part of the approval process in the EU, biosimilars have to demonstrate comparability to the originator product in terms of safety, efficacy and quality through an extensive comparability exercise, based on strict guidelines set by the authorities. Regulators will only approve a biosimilar based on data which allows the regulators to conclude that there are no clinically meaningful differences between the reference product and the biosimilar.

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In the US, the regulatory pathway for the approval of a biosimilar product was established under the 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 as soon as 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 relatively new and some aspects remain 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, originator 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.

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," and " Sandoz Production." The following table sets forth our major headquarters and most significant production and research and development

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facilities by division. A number of the facilities associated with our former Vaccines, OTC and Animal Health Divisions were transferred as part of the portfolio transformation transactions completed in 2015.

Location/Division	Size of Site (in square meters)	Major Activity
Major facilities:		
Pharmaceuticals		
East Hanover, New Jersey	400,000	Division US headquarters, research and development
Changshu (Suzhou), China	230,000	Technical research, development and manufacturing of drug substances and drug intermediates
Cambridge, Massachusetts	212,000	Global NIBR 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
Ringaskiddy, Ireland	85,000	Production of drug substances and drug intermediates
Stein, Switzerland	64,700	Production of sterile vials, pre-filled syringes and ampoules, and of inhalation capsules, tablets and transdermals, and of active pharmaceutical ingredients
Grimsby, UK	64,000	Production of drug substances and drug intermediates
Huningue, France	35,000	Production of drug substances for clinical and commercial supply
Barbera, Spain	33,000	Production of tablets, capsules and inhalation products
Basel, Switzerland Schweizerhalle	31,700	Production of drug substances and drug intermediates

Wehr, Germany	31,700	Production of tablets, creams and ointments

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Location/Division	Size of Site (in square meters)	Major Activity
Shanghai, China	14,200	Research and development
Morris Plains, New Jersey	14,000	Production of personalized cell therapy
Alcon		
Fort Worth, Texas	252,800	Division headquarters, production, research and development for Ophthalmic Pharmaceuticals, Vision Care, Surgical
Grosswallstadt, Germany	82,400	Production, research and development for Vision Care
Johns Creek, Georgia	73,400	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
Barleben, Germany	340,000	Production of broad range of finished dosage forms
Ljubljana, Slovenia	83,000	Production of broad range of finished solid and sterile dosage forms
Holzkirchen, Germany	72,300	Division headquarters, production of oral films, transdermal delivery systems, matrix patches, product development
Stryków, Poland	45,000	Production of broad range of bulk oral solid forms
Rudolstadt, Germany	44,000	Development and production of respiratory technologies and ophthalmics

Princeton, New Jersey	14,300	Division US headquarters

In 2010, we announced a Group-wide review of our manufacturing footprint. In 2015, and continuing into 2016, we continued to optimize our manufacturing footprint, bringing the total number of production

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sites that have been or are in the process of being restructured, exited or divested as part of these activities to 25 for our continuing operations. These steps help us balance production capacity and further increase efficiency. We have recorded exceptional charges of $375 million in 2015, bringing the total charges to $950 million since the program began for our continuing operations. As part of this initiative we announced in 2015 the closing of our Pharmaceuticals Division facility in Resende, Brazil and plans to exit our Sandoz Division plants in Gerlingen and Frankfurt, Germany, and Turbhe, India. We also announced downsizing at a Pharmaceutical Division site in Ringaskiddy, Ireland. In addition, we finalized the divestment of our Alcon Division manufacturing operations in Kaysersberg, France, and the divestment of our pharmaceutical manufacturing site in Taboão da Serra, Brazil.

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 2015, 17 new buildings had begun operations, eight of them laboratory buildings. The current phase of the long term redevelopment of our St. Johann site is expected to be completed in 2016. 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 and construction is expected to begin in 2016. 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, 2015, 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 the Campus project and the relocation of production facilities to other sites in the Basel region through 2017. 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 one 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, 2015, two laboratory buildings and two office buildings of the first phase of the project are completed. In addition, the other two office buildings which are part of phase one are nearly complete with testing, commissioning and resolution of punch list items in progress. Through December 31, 2015, the total amount paid and committed to be paid on the CNIBR Project is equivalent to $844 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 2015, construction is complete and associates will begin moving into the new buildings. Through December 31, 2015, the total amount paid and committed to be paid on the NIBR Project is $743 million.

In 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 $600 million. The new facility is planned to replace an older facility. In addition, Novartis plans to invest in new technologies and packaging facilities for pharmaceuticals at Stein. Stein is planned to be a technological competence center for both sterile and solid dosage form drugs,

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while Novartis plans to expand the site's strategic role as a key platform for global launches of new pharmaceutical products. Through December 31, 2015, the total amount paid and committed to be paid on this project is equivalent to $554 million.

In 2012, we announced the planned construction of a new state-of-the-art biotechnology production site in Singapore with a planned investment of over $700 million. The new facility will focus on drug substance manufacturing based on cell culture technology. Ground was broken in February 2013 and construction was completed in the third quarter of 2015 for phase one of the project. We expect phase one of this project to be operational in 2017 and phase two in 2019. 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, 2015, the total amount paid and committed to be paid on this project is equivalent to $452 million.

In 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. Through December 31, 2015, the total amount paid and committed to be paid on this project is $33 million.

A second expansion of the Johns Creek, Georgia facility was approved in the third quarter of 2014 to add nine production lines for *Dailies* and *Dailies Total1* contact lenses. This project is expected to be completed by the third quarter of 2017. Through December 31, 2015, the total amount paid and committed to be paid on this project is $219 million.

The Alcon Division began an expansion of its Singapore facility in 2014 for contact lens manufacturing. The expansion is expected to add 16,000 square meters to the existing production lines. Through December 31, 2015, the total amount paid and committed to be paid on this project is equivalent to $95 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, in some cases over many years, 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."

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Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

5.A Operating Results

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

OVERVIEW

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio includes innovative medicines, eye care products and cost-saving generic pharmaceuticals.

Following the completion of a series of transactions in 2014 and 2015, the Group's portfolio is organized into three global operating divisions. In addition, we separately report the results of Corporate activities. The disclosure in this Item focuses on these continuing operations, which are made up of Pharmaceuticals, Alcon, Sandoz and Corporate activities. In addition, from March 2, 2015, the date of the completion of a series of transactions with GSK, continuing operations also includes the results from the oncology assets acquired from GSK and the 36.5% interest in the GSK consumer healthcare joint venture (the latter reported as an investment in associated companies). We sold our Vaccines Division, excluding our influenza business, to GSK. Our influenza vaccines business was sold to CSL and our Animal Health Division was sold to Lilly. For more detail on these transactions see, "Item 10.C Material Contracts."

Continuing Operations:

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

Discontinued Operations:

- Vaccines and Diagnostics: Preventive human vaccines and blood-testing diagnostics
- Consumer Health: OTC (over-the-counter medicines) and Animal Health
- 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 from Corporate activities 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

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related to post-employment benefits, environmental remediation liabilities, charitable activities, donations and sponsorships.

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

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, and is headquartered in Cambridge, Massachusetts. More than 6,000 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, Singapore and China. For more information about NIBR, see " Pharmaceuticals Research and Development Research program," below.

Novartis Business Services (NBS), our shared services organization, consolidates support services across Novartis divisions, helping to drive efficiency, standardization and simplification. NBS includes six service domains: human resources services, real estate and facility management, procurement, information technology, product lifecycle services and financial reporting and accounting operations. NBS has approximately 9,500 associates. Moving from division-specific services to a cross-divisional model, NBS continues to scale up the offshoring of transactional services to its five selected Global Service Centers in Mexico City, Mexico; Kuala Lumpur, Malaysia; Prague, Czech Republic; Hyderabad, India; and Dublin, Ireland.

Our continuing operations achieved net sales of $49.4 billion in 2015, while net income from continuing operations amounted to $7.0 billion. Research & Development expenditure in 2015 amounted to $8.9 billion ($8.7 billion excluding impairment and amortization charges). Of total net sales from continuing operations, $12.4 billion, or 25%, came from Emerging Growth Markets, and $37.0 billion, or 75%, 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 118,700 full-time equivalent associates as of December 31, 2015. Our products are available in approximately 180 countries around the world.

In September 2015, Novartis announced the launch of Novartis Access, a portfolio of 15 medicines to treat chronic diseases in low- and middle-income countries. The portfolio addresses cardiovascular diseases, diabetes, respiratory illnesses, and breast cancer and will be offered to governments, non-governmental organizations (NGOs) and other public-sector healthcare providers for $1 per treatment, per month.

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. Our Pharmaceuticals Division also includes a franchise focused on the development and commercialization of Cell and Gene Therapies.

On March 2, 2015, we completed the acquisition of the oncology products of GSK, together with certain related assets. In addition, we acquired 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.

In 2015, the Pharmaceuticals Division accounted for $30.4 billion, or 62%, of Group net sales, and for $7.6 billion, or 81%, of Group operating income (excluding Corporate income and expense, net).

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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-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 2015, Alcon accounted for $9.8 billion, or 20%, of Group net sales, and for $0.8 billion, or 8%, 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 intermediary products including active pharmaceutical ingredients. 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 areas of cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies. Finished dosage form anti-infectives sold to third parties are also part of Retail Generics. 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 and provides biotechnology manufacturing services to other companies, and in Oncology Injectables, Sandoz develops, manufactures and markets cytotoxic products for the hospital market.

In 2015, Sandoz accounted for $9.2 billion, or 18%, of Group net sales, and for $1.0 billion, or 11%, of Group operating income (excluding Corporate income and expense, net).

Discontinued Operations:

Vaccines and Diagnostics Division

Prior to the completion of certain transactions in 2014 and 2015, our Vaccines and Diagnostics Division researched, developed, manufactured, distributed and sold human vaccines and blood-testing products worldwide. On January 9, 2014, we completed the divestment of our blood transfusion diagnostics unit to Grifols S.A. On March 2, 2015, we completed the divestment of our Vaccines Division (excluding its influenza vaccines business) to GSK. On July 31, 2015, we completed the divestment of our influenza vaccines business to CSL Limited.

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Consumer Health

Prior to the completion of certain transactions in 2015, Consumer Health consisted of our OTC (Over-the-Counter) and Animal Health Divisions. On January 1, 2015 we completed the divestment of our Animal Health Division to Lilly. On March 2, 2015, we completed the divestment of our OTC Division, which we contributed to a new consumer healthcare joint venture with GSK, of which we own 36.5%.

OPPORTUNITY AND RISK SUMMARY

Our financial results are affected to varying degrees by external factors. The aging of the global population and rising rates of chronic diseases are driving demand for healthcare worldwide, as well as for treatments that Novartis provides. Continued growth in healthcare spending is contributing to increased scrutiny on drug pricing by governments, media and consumers, but also to increased demand for lower-cost treatment options, such as those produced by our generics division, Sandoz. Advances in science and technology are opening new opportunities to develop treatments tailored for individual patients.

At the same time, the loss of market exclusivity and the introduction of branded and generic competitors could significantly erode sales of our innovative products. Heightened regulatory requirements and the inherent complexity of our industry could lead to difficulties in bringing products to market, while increased pressure on pricing could impact our ability to generate returns and invest for the future. The growing 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 and constant currency results. These measures assist us in evaluating our ongoing performance from year to year and we believe this additional information is useful to investors in understanding our business.

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

We present information about our net sales and other key figures relating to operating and net income in constant currencies (cc). We calculate constant currency net sales and operating income 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.

The core results, constant currencies 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.

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2015 Compared to 2014

Group Overview

Key figures

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales to third parties from continuing operations	**49,414**	**52,180**	**(5)**	**5**
Sales to discontinued segments	26	239	(89)	(88)
Net sales from continuing operations	**49,440**	**52,419**	**(6)**	**4**
Other revenues	947	1,215	(22)	(22)
Cost of goods sold	(17,404)	(17,345)	0	(8)
Gross profit from continuing operations	**32,983**	**36,289**	**(9)**	**2**
Marketing & Sales	(11,772)	(12,377)	5	(5)
Research & Development	(8,935)	(9,086)	2	(3)
General & Administration	(2,475)	(2,616)	5	(1)
Other income	2,049	1,391	47	55
Other expense	(2,873)	(2,512)	(14)	(24)
Operating income from continuing operations	**8,977**	**11,089**	**(19)**	**(2)**
Return on net sales (%)	18.2	21.3		
Income from associated companies	266	1,918	(86)	(86)
Interest expense	(655)	(704)	7	2
Other financial income and expense	(454)	(31)	nm	nm
Income before taxes from continuing operations	**8,134**	**12,272**	**(34)**	**(17)**
Taxes	(1,106)	(1,545)	28	10
Net income from continuing operations	**7,028**	**10,727**	**(34)**	**(18)**
Net income/loss from discontinued operations	10,766	(447)	nm	nm
Net income	**17,794**	**10,280**	**73**	**91**
Attributable to:				
Shareholders of Novartis AG	*17,783*	*10,210*	*74*	*92*
Non-controlling interests	*11*	*70*	*(84)*	*(84)*
Basic earnings per share ($) from continuing operations	**2.92**	**4.39**	**(33)**	**(17)**
Basic earnings per share ($) from discontinued operations	4.48	(0.18)	nm	nm
Total basic earnings per share ($)	**7.40**	**4.21**	**76**	**94**
Free cash flow from continuing operations	**9,259**	**10,934**	**(15)**	
Free cash flow	**9,029**	**10,762**	**(16)**	

nm = not meaningful

Novartis delivered solid financial performance in 2015, driven by our continued success with growth products and expansion in emerging growth markets, which helped offset the effects of generic competition of approximately $2.2 billion. As a result, we achieved net sales to third parties from continuing operations of $49.4 billion (5%, +5% cc). Growth in constant currencies has been more than

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offset by negative currency impacts driven by the strengthening of the US dollar versus the euro, Japanese yen and major emerging market currencies.

Operating income decreased by 2% in constant currencies to $9.0 billion (19%, 2% cc), mainly due to the amortization of the new oncology assets in Pharmaceuticals. In addition, an exceptional expense of $400 million for a settlement of the specialty pharmacies case in the Southern District of New York was recorded in 2015, whereas the prior-year benefitted from a one-time commercial settlement gain of $302 million and $248 million gain from selling a Novartis Venture Fund investment. Operating income margin was 18.2 percent of net sales.

Net income from continuing operations was $7.0 billion, declining more than operating income (34%, 18% cc) mainly due to higher financial expense driven by $0.4 billion exceptional charges related to Venezuela and lower income from associated companies, which included in the prior year a gain of $0.8 billion from the sale of the shares of Idenix Pharmaceuticals, Inc., US (Idenix) to Merck & Co., US, and a gain of $0.4 billion from the divestment of the shareholding in LTS Lohmann Therapie-Systeme AG, Germany (LTS).

Basic earnings per share from continuing operations decreased 33% (17% cc) to $2.92, declining less than net income from continuing operations due to the lower number of average outstanding shares.

Free Cash Flow from continuing operations decreased 15% to $9.3 billion, primarily due to negative currency impact on operations.

Net income from discontinued operations amounted to $10.8 billion in 2015, which included $12.7 billion of pre-tax divestment gains and the operational results of the divested businesses until the respective dates of completion of the transactions, compared to a net loss of $447 million in 2014. For more information on discontinued operations see " Factors Affecting Comparability of Year-On-Year Results of Operations", below and "Item 18. Financial Statements Note 30".

For the total Group, net income amounted to $17.8 billion in 2015 compared to $10.3 billion in 2014, impacted by the exceptional divestment gains included in net income from the discontinued operations. Basic earnings per share increased to $7.40 from $4.21 in the prior year and free cash flow for the total Group amounted to $9.0 billion.

Growth

Across our divisions, our portfolio of growth products continued to support performance in 2015. Sales of growth products increased 17% to $16.6 billion, or 34% of net sales, demonstrating our ability to renew our product portfolio and helping offset the impact of patent expirations. In our Pharmaceuticals Division, sales of growth products increased 33% (cc) and accounted for 44% of net sales, up from 36% in 2014.

Pharmaceutical growth products in 2015 included *Gilenya* ($2.8 billion, +21% cc), our oral therapy for multiple sclerosis; *Tasigna* ($1.6 billion, +16% cc), a treatment for chronic myeloid leukemia; and *Afinitor* ($1.6 billion, +10% cc), a treatment for several types of cancer.

Although overall Alcon performance lagged in 2015, some products continued to do well. Alcon saw continued growth in sales of its innovative *Dailies Total1* contact lenses, as well as double-digit growth in glaucoma fixed-dose combination products and *Systane* for dry eye. Sales of disposable cataract and vitreoretinal surgical supplies also grew.

In the Sandoz Division, sales of biopharmaceuticals, including biosimilar follow-on versions of complex biologic drugs, rose 39% (cc) to $772 million globally.

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Efforts to expand in emerging growth markets[2] such as those in Asia, Africa and Latin America continued to deliver results, although growth moderated as overall economic activity slowed in China, Brazil, India and elsewhere. Net sales in emerging markets rose 7% (cc) to $12.4 billion, led by Turkey, up 14% (cc), and Brazil, up 12% (cc).

Productivity

Last year Novartis continued to find synergies across divisions in our ongoing effort to improve productivity. Total productivity gains reached $3.2 billion in 2015, 6% of net sales. Novartis Business Services (NBS), the cross-divisional services organization that ramped up last year, played a key role in achieving this result. NBS continues to scale up the offshoring of services to global service centers, while outsourcing selected services to third parties.

The biggest savings came from our procurement efforts, through which we saved more than $1.7 billion on goods and services, or about 8% of the spending managed by Novartis procurement organizations.

An ongoing effort begun in 2010 to optimize our global manufacturing network continues to yield results. In 2015, we announced plans to exit Sandoz manufacturing sites in Frankfurt and Gerlingen, Germany, as well as in Turbhe, India. We also closed a Pharmaceuticals Division facility in Resende, Brazil, divested an Alcon site in Kaysersberg, France, as well as a pharmaceutical site in Taboão da Serra, Brazil, and announced the downsizing of a Pharmaceuticals Division site in Ringaskiddy, Ireland. To date, 25 sites in our continuing operations have been or are being restructured or divested. These steps help us balance production capacity and further increase efficiency.

Net Sales by Segment

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

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Pharmaceuticals	**30,445**	**31,791**	**(4)**	**6**
Alcon	**9,812**	**10,827**	**(9)**	**(1)**
Sandoz	**9,157**	**9,562**	**(4)**	**7**
Net sales to third parties from continuing operations	**49,414**	**52,180**	**(5)**	**5**

Pharmaceuticals

Pharmaceuticals delivered net sales of $30.4 billion (4%, +6% in constant currencies, or cc) as increased volumes, including from the oncology portfolio acquired from GlaxoSmithKline (GSK) in 2015, countered the impact of greater generic competition, which reduced sales by 7.0 percentage points.

Growth products generated $13.5 billion of division net sales, growing 33% (cc) compared to last year. These products which include *Gilenya*, *Tasigna*, *Ultibro*, the combination of *Tafinlar + Mekinist*, *Jakavi, Revolade* and *Cosentyx* contributed 44% of division net sales, compared to 36% in 2014.

Sales in emerging growth markets increased 9% (cc) to $7.8 billion.

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2 Growth products are products launched in 2010 or later, or products with exclusively until at least 2019 in key markets (EU, US, Japan), except Sandoz (launched in the last 24 months). Emerging growth markets are all markets except the US, Canada, Western Europe, Japan, Australia and New Zealand.

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Highlights in 2015 included regulatory approval in the US and EU for *Entresto* (formerly LCZ696) for chronic heart failure; *Farydak* for multiple myeloma; and *Tafinlar + Mekinist*, the first combination therapy for metastatic melanoma. *Cosentyx,* which was successfully launched in the US and EU in 2015 to treat psoriasis, also received approval in Europe to treat psoriatic arthritis and ankylosing spondylitis.

Oncology

Oncology sales rose 15% (+24% cc) to $13.5 billion, boosted by the newly acquired portfolio from GSK and continued growth in our existing products. By brand, growth drivers included *Afinitor*, up 10% (cc) to $1.6 billion; *Tasigna*, up 16% (cc) to $1.6 billion; and *Jakavi*, up 71% (cc) to $410 million.

Neuroscience

Neuroscience sales were $3.9 billion (4%, +5% cc), with *Gilenya* rising 12% (+21% cc) to $2.8 billion and more than offsetting declines in *Exelon/Exelon Patch* due to generic competition.

Retina

Sales in Retina were $2.1 billion (16%, 3% cc), driven mainly by lower sales of *Lucentis,* which faced increased competitive pressure in Japan and some European markets.

Immunology and Dermatology

Sales in Immunology and Dermatology were $2.1 billion (0%, +11% cc). *Cosentyx* made a strong start after launching in February, reaching sales of $261 million. Additionally, *Zortress/Certican* rose 2% (+17% cc) to $335 million, and *Ilaris* increased 19% (+30% cc), helping offset declines in other products primarily stemming from generic competition.

Respiratory

Respiratory sales were $1.6 billion (+1%, +17% cc). We had sales of $0.6 billion (+19%, +40% cc) for our portfolio of drugs for chronic obstructive pulmonary disease (COPD), including *Onbrez Breezhaler/Arcapta Neohaler*, *Seebri Breezhaler* and *Ultibro Breezhaler.* Sales of *Xolair* reached $0.8 billion (3%, +14% cc), including as a treatment for chronic hives.

Cardio-Metabolic

Entresto was launched in the US in the third quarter and full-year sales reached $21 million. *Galvus* sales were $1.1 billion (7%, +8% cc).

Established Medicines

Established medicines such as *Diovan* ($1.3 billion, 40% cc) and *Exforge* ($1.0 billion, 15% cc) continued to see declines as a result of generic competition.

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TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2015

Brands	Business Franchise	Indication	US $ m	US % change in constant currencies	Rest of world $ m	Rest of world % change in constant currencies	Total $ m	Total % change in $	Total % change in constant currencies
Gleevec/Glivec	Oncology	Chronic myeloid leukemia and GIST	2,533	17	2,125	(5)	**4,658**	**(2)**	**5**
Gilenya	Neuroscience	Relapsing multiple sclerosis	1,497	26	1,279	17	**2,776**	**12**	**21**
Lucentis	Retina	Age-related macular degeneration			2,060	(2)	**2,060**	**(16)**	**(2)**
Tasigna	Oncology	Chronic myeloid leukemia	661	22	971	12	**1,632**	**7**	**16**
Sandostatin	Oncology	Carcinoid tumors and Acromegaly	823	10	807	5	**1,630**	**(1)**	**7**
Afinitor/Votubia	Oncology	Breast cancer / TSC	892	11	715	9	**1,607**	**2**	**10**
Diovan/Co Diovan	Established Medicines	Hypertension	254	(74)	1,030	(17)	**1,284**	**(45)**	**(40)**
Galvus	Cardio-Metabolic	Diabetes			1,140	8	**1,140**	**(7)**	**8**
Exforge	Established Medicines	Hypertension	67	(76)	980	1	**1,047**	**(25)**	**(15)**
Exjade	Oncology	Chronic iron overload	365	19	552	3	**917**	**(1)**	**8**
Xolair [(1)]	Respiratory	Asthma			755	14	**755**	**(3)**	**14**
Exelon/Exelon **Patch**	Neuroscience	Alzheimer's disease	340	(30)	388	(13)	**728**	**(28)**	**(21)**
Neoral/Sandimmun(e)	Immunology and Dermatology	Transplantation	47	(15)	523	(5)	**570**	**(17)**	**(6)**
Votrient	Oncology	Renal cell carcinoma	287	nm	278	nm	**565**	**nm**	**nm**
Voltaren (excl. other divisions)	Established Medicines	Inflammation/pain			558	0	**558**	**(12)**	**0**
Tafinlar/Mekinist	Oncology	Melanoma	267	nm	186	nm	**453**	**nm**	**nm**
Myfortic	Immunology and Dermatology	Transplantation	109	(27)	332	0	**441**	**(19)**	**(8)**
Jakavi	Oncology	Myelofibrosis			410	71	**410**	**47**	**71**
Promacta/Revolade	Oncology	Immune thrombocytopenic purpura	196	nm	206	nm	**402**	**nm**	**nm**
Ritalin/Focalin	Established Medicines	Attention deficit/ hyperactivity disorder	226	(31)	139	1	**365**	**(26)**	**(20)**
Top 20 products total			**8,564**	**7**	**15,434**	**7**	**23,998**	**(3)**	**7**
Rest of portfolio			1,715	(2)	4,732	4	**6,447**	**(9)**	**2**
Total Division sales			**10,279**	**5**	**20,166**	**6**	**30,445**	**(4)**	**6**

(1) Net sales reflect *Xolair* sales for all indications (e.g. including *Xolair* SAA and *Xolair* CSU, which are managed by the Immunology and Dermatology franchise).

nm = not meaningful

Gleevec/Glivec ($4.7 billion, +5% cc) 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 growth 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* expired 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 commencing on February 1, 2016.

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Gilenya ($2.8 billion, +21% cc), the first once-daily oral therapy to treat relapsing forms of multiple sclerosis (RMS), continued to outgrow the market, achieving double-digit growth in 2015 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. In an expanding oral market with multiple options, *Gilenya* is the only oral disease-modifying therapy (DMT) to impact the course of RMS with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. *Gilenya* has an overall positive benefit-risk profile with over ten years of safety experience. As of November 30, 2015, *Gilenya* has been used to treat approximately 134,000 patients in clinical trials and in a post-marketing setting, with a total patient exposure of approximately 289,000 patient years. *Gilenya* is currently approved in over 80 countries around the world. *Gilenya* is licensed from Mitsubishi Tanabe Pharma.

Lucentis ($2.1 billion, 2% cc) sales were impacted by increased competition in Japan and in some European markets, which offset growth opportunities in Emerging Markets. *Lucentis* maintained a strong ex-US market position across indications but was impacted by competitive pressures in the neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) indications, partially offset by continued growth in macular edema secondary to central and branch retinal vein occlusion (CRVO and BRVO), and choroidal neovascularization secondary to pathologic myopia (mCNV) indications. *Lucentis* is an anti-VEGF therapy licensed in many countries for the treatment of the following five ocular indications: nAMD, DME, CRVO, BRVO, and mCNV. *Lucentis* is approved in more than 100 countries to treat patients with the first four conditions, and in more than 80 countries for mCNV. In 2015, *Lucentis* obtained reimbursement for DME and RVO in Australia. It is the only anti-VEGF treatment delivered in a pre-filled syringe and approved for a treat & extend regimen across all indications in Europe. Since its launch in 2006, there have been more than 3.7 million patient-treatment years of exposure for *Lucentis* with more than 22 million injections. *Lucentis* is an anti-VEGF therapy specifically designed for the eye, minimizing systemic exposure, that has demonstrated significant efficacy with individualized dosing in its five licensed indications and has a well-established safety profile supported by extensive clinical studies and real-world experience. *Lucentis* is licensed from Genentech, and Novartis holds the rights to commercialize the product outside the US. Genentech holds the rights to commercialize *Lucentis* in the US.

Tasigna ($1.6 billion, +16% cc) performance was driven by strong growth in the US and other markets. *Tasigna* is currently approved as a first-line therapy for newly diagnosed patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (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*.

Sandostatin ($1.6 billion, +7% cc) continued to benefit from the increasing use of *Sandostatin LAR* (long acting release) in key markets and from the launch of the enhanced presentation (now approved in 69 countries) which includes a diluent, safety needle and vial adapter. *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 more than 60 countries).

Afinitor/Votubia ($1.6 billion, +10% cc) performance was driven by strong growth in the US, Japan and other markets. *Afinitor* is an oral inhibitor of the mTOR pathway approved in combination with exemestane for the treatment of patients with HR+/HER2 advanced breast cancer after failure with a

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non-steroidal aromatase inhibitor (NSAI), for advanced renal cell carcinoma (RCC) following vascular endothelial growth factor-targeted therapy (after failure of sunitinib and sorafenib in the US) and for the treatment of advanced pancreatic neuroendocrine tumors (NET). *Afinitor* is also approved for treatment of patients with subependymal giant cell astrocytoma (SEGA) and renal angiomyolipoma associated with tuberous sclerosis complex (TSC), including as a dispersible tablet formulation in the US and EU for SEGA. Everolimus is also in Phase III development for patients with nonfunctional gastrointestinal and lung NET, HER2+ breast cancer, diffuse large B-cell lymphoma and TSC-related seizures. 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.

Diovan Group ($1.3 billion, 40% cc), consisting of *Diovan* monotherapy and the combination product *Co-Diovan/Diovan* HCT, continues to retain a blockbuster status despite 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). Sales continued to grow in Emerging Growth Markets, including China and selected countries in Latin America, Asia Pacific and Africa, partially compensating for loss of exclusivity in the US and the EU.

Galvus Group ($1.1 billion, +8% cc), includes *Galvus*, an oral treatment for type 2 diabetes, and *Eucreas*, a single-pill combination of vildagliptin (the active ingredient in *Galvus*) and metformin. *Galvus* delivered solid growth with major milestones including approval of the *Galvus* monotherapy indication in China in April 2015. In September 2015, the Japanese HA PMDA approved *Eucreas* (*EquMet*), the first single-pill combination of a DPP4 inhibitor and metformin approved in this market. The focus for *Galvus* remains on patients whose diabetes remains uncontrolled on metformin, earlier treatment intensification as well as on an expansion of usage in key segments such as elderly and renal-impaired patients. *Galvus* Group is currently approved in more than 125 countries.

Exforge Group ($1.0 billion, 15% 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 *ExforgeHCT*, a single pill combining an ARB (valsartan), calcium channel blocker (amlodipine) and a diuretic (hydrochlorothiazide) three widely prescribed blood pressure treatments. *Exforge* lost exclusivity in October 2014 and *ExforgeHCT* in November 2014 in the US. Outside the US, *Exforge HCT* is growing across all regions, showing significantly high growth in emerging markets. *Exforge* continues to grow with double-digit growth in China and a number of emerging markets. *Exforge* is now available in more than 100 countries and *ExforgeHCT* is available in over 77 countries.

Exjade ($917 million, +8% cc), a once-daily dispersible tablet for chronic transfusional iron overload saw sales increases in the US and Asia augmented by the March 2015 approval in the US of *Jadenu*, an oral tablet formulation that can be swallowed or crushed, and was approved by the FDA in 2015. Regulatory applications for *Jadenu* have been submitted in the EU, Canada, Switzerland, and many other countries. *Exjade,* first approved in 2005 and now approved in more than 100 countries, is also approved for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia in more than 70 countries, with additional regulatory reviews underway. *Jadenu* is also approved for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia in the US.

Xolair ($755 million, +14% 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. Its sales continued to grow strongly in Canada, Europe and Latin America. *Xolair* is also approved in the EU, Switzerland and over 40 other countries as a treatment for chronic spontaneous urticaria (CSU), also known as chronic idiopathic urticaria (CIU), for which it is approved in the US and now Canada and Australia. Novartis co-promotes *Xolair* with Genentech in the US and shares a portion of the operating income, but does not book US sales.

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Exelon/Exelon Patch ($728 million, 21% cc) sales declined due to generic competition for *ExelonPatch* in the EU and now in the US. *ExelonPatch* 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. *ExelonPatch* is also indicated for the treatment of patients with severe AD in 14 countries, including the US.

Neoral/Sandimmun ($570 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. Although sales are declining due to generic competition and mandatory price reductions, most notably in Europe and Japan, the decrease is not as rapid as has been the case in other therapeutic areas, due to the special characteristics of the solid organ transplant market.

Votrient ($565 million) is a small molecule tyrosine kinase inhibitor that targets a number of intracellular proteins to limit tumor growth and cell survival. Acquired from GSK in 2015, *Votrient* is approved in the US for the treatment of patients with advanced renal cell carcinoma (aRCC), and in the EU for first-line treatment of adult patients with aRCC and for patients who have received prior cytokine therapy for advanced disease. RCC is the most common type of kidney cancer in adults, and nearly one-fifth of patients have aRCC at the time of diagnosis. *Votrient* is also indicated for patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The efficacy of *Votrient* for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated. STS is a type of cancer which can arise from a wide variety of soft tissues including muscle, fat, blood vessel and nerves. *Votrient* is approved in 99 countries worldwide for aRCC and in 87 countries for aSTS.

Voltaren/Cataflam ($558 million, 0% 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 the product and our Alcon Division markets *Voltaren* for ophthalmic indications.

Tafinlar + Mekinist ($453 million) achieved strong growth in sales. Acquired from GSK in 2015, this combination is the first of its kind for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, as detected by a validated test, in the US, EU, Canada and several other markets. In August, the combination of *Tafinlar + Mekinist* was approved in Europe for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation and in November, this combination received regular approval in the US based on the completion of two Phase III confirmatory trials. The combination was previously approved in the US under accelerated approval. *Tafinlar* targets the serine/threonine kinase BRAF in the RAS/RAF/MEK/ERK pathway and *Mekinist* targets the threonine/tyrosine kinases MEK1 and MEK2 in the MAP kinase pathway, resulting in dual blockade of this pathway, improving the clinical efficacy of the treatment. This is the first combination of BRAF/MEK inhibitors to achieve a median overall survival of more than two years in two Phase III studies in BRAF V600 mutation positive unresectable or metastatic melanoma patients. *Tafinlar + Mekinist* are also approved as single agents for the treatment of patients with unresectable or metastatic melanoma in more than 45 and 30 countries worldwide, respectively. In addition, *Tafinlar* also has Breakthrough Therapy designation from the FDA for treatment of non-small cell lung cancer (NSCLC) patients with BRAF V600E mutations who have received at least one prior line of platinum-containing chemotherapy. In July, the combination therapy *Tafinlar + Mekinist* also received Breakthrough Therapy designation from the FDA for NSCLC patients with BRAF V600E mutations.

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Myfortic ($441 million, 8% cc), a transplantation medicine, is available in more than 90 countries to prevent organ rejection in adult kidney transplant patients. Although it has experienced declining sales after the expected launch of generic competition in the US in early 2014, the decrease is not as rapid as has been the case in other therapeutic areas, due to the special characteristics of the solid organ transplant market. *Myfortic* continued to grow in some geographies where generic competition has not yet begun. Marketing authorizations for generic competitors have been granted in European countries.

Jakavi ($410 million, +71% cc) performance was driven by strong volume growth across multiple markets. *Jakavi* 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 95 countries, including EU member states, Japan and Canada. In March 2015, the EC approved *Jakavi* for the treatment of adult patients with polycythemia vera (PV) who are resistant to or intolerant of hydroxyurea. *Jakavi* is the first targeted treatment approved by the EC for these patients. More than 45 countries have approved *Jakavi* in the PV indication, including Switzerland, Canada and Japan, and regulatory applications have been submitted in other countries. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US.

Promacta/Revolade ($402 million) performance was driven by strong growth in the US and other markets. Acquired from GSK in 2015, *Promacta* is marketed under the brand name *Promacta* in the US and *Revolade* in most countries outside the US. It is the only approved once-daily oral thrombopoietin receptor agonist. In August 2015, the US FDA approved an expanded use for *Promacta* to include children 1 year of age and older with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. The updated label includes a new oral suspension formulation of *Promacta* that is designed for younger children who may not be able to swallow tablets. *Revolade* is currently under review for this same indication with the EMA. In December, Novartis received a positive CHMP opinion on a potential update to the adult chronic ITP indication with regards to the use of *Revolade* in non-splenectomised patients; the EMA decision is expected in February 2016. *Revolade* was approved by the European Commission in September 2015 for the treatment of adults with acquired severe aplastic anemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for hematopoietic stem cell transplant.

Ritalin/Focalin ($365 million, 20% 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. To date in 2015, *Ritalin LA* has been granted the adult ADHD indication in over 20 countries. *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. Most strengths of *Ritalin LA* and *Focalin* are subject to generic competition in the US.

Alcon

Alcon net sales in 2015 were $9.8 billion (9%, 1% in constant currencies, or cc). Regionally, sales were flat in Japan and rose in Latin America and the Caribbean. In Europe, the Middle East and Africa, sales rose 1% (cc), with strong sales of recently launched contact lenses, including *Dailies Total1* and *Air Optix Colors*, offset by declines in surgical equipment.

Sales in North America declined 3%, mainly due to increased generic competition for some pharmaceutical products and soft surgical equipment sales. In Asia and Russia, sales declined 5% (cc), driven by a significant market slowdown, with weak performance in China, India and Southeast Asia.

To accelerate growth, we are taking concerted action on two fronts. For the Surgical and Vision Care businesses, we have identified key actions as part of a growth plan. They include steps to optimize

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innovation in intraocular lenses (IOLs) for cataract surgery, prioritizing and investing in the development of promising new products, and improving the effectiveness of our sales force.

In addition, we plan to strengthen our ophthalmic medicines business by transferring pharmaceutical products from Alcon to our Pharmaceuticals Division, combining expertise in pharmaceuticals development and marketing with the strong Alcon brand.

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Constant currencies change
	$ m	$ m	%	%
Surgical				
Cataract products	2,853	3,174	(10)	(2)
of which IOLs	*1,099*	*1,264*	*(13)*	*(4)*
Vitreoretinal products	594	615	(3)	6
Refractive/other	251	284	(12)	(5)
Total	**3,698**	**4,073**	**(9)**	**(1)**
Ophthalmic Pharmaceuticals				
Glaucoma	1,196	1,319	(9)	2
Allergy/otic/nasal	780	887	(12)	(8)
Infection/inflammation	1,011	1,066	(5)	2
Dry eye	583	608	(4)	6
Other	243	331	(27)	(15)
Total	**3,813**	**4,211**	**(9)**	**0**
Vision Care				
Contact lenses	1,743	1,897	(8)	1
Contact lens care	558	646	(14)	(8)
Total	**2,301**	**2,543**	**(10)**	**(2)**
Total net sales	**9,812**	**10,827**	**(9)**	**(1)**

Surgical

Surgical franchise sales were $3.7 billion (9%, 1% cc). Solid sales of cataract and vitreoretinal disposable surgical supplies were offset by competitive pressure on IOL sales, as well as a slowdown in equipment purchases in the US and emerging markets, particularly Asia. Launches in 2015 of our *UltraSert* pre-loaded and *PanOptix* trifocal IOLs in Europe, as well as regulatory approval of *UltraSert* pre-loaded IOLs in the US, provide an opportunity to renew growth in this segment.

Ophthalmic Pharmaceuticals

Ophthalmic Pharmaceuticals sales were $3.8 billion (9%, 0% cc). In glaucoma products, strong performance of fixed-dose combination products, including *Azarga* and *Simbrinza,* was offset by generic competition for monotherapies. *Systane* eye drops to treat the symptoms of dry eye saw sales grow in the US and Europe, the Middle East and Africa, with softer sales across emerging markets. Sales of allergy, nasal and ear medicines declined, driven by continued generic competition in the US.

Vision Care

Vision Care sales were $2.3 billion (10%, 2% cc). Contact lens sales reached $1.7 billion (8%, +1% cc), with strong sales of innovative lenses, particularly *Dailies Total1* and *Air Optix Colors,* offset by

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declines in older products. Sales of contact lens solutions were $0.6 billion (14%, 8% cc), affected by ongoing market shifts to daily disposable lenses, as well as competitive pressure in the US.

Sandoz

In 2015, Sandoz had net sales of $9.2 billion (4%, +7% in constant currencies, or cc, from the prior year), driven by a 15.0 percentage-point increase in volume, more than offsetting 8.0 percentage points of price erosion. Performance was driven by strong sales growth in the US (+10% cc), Asia Pacific (+13% cc), Latin America (+18% cc), and Middle East and Africa (+13% cc). Sales in Western Europe grew 3% (cc), with Germany growing 5% (cc).

Sandoz continued to strengthen its global leadership position in biopharmaceuticals, which include medicines that are difficult to develop and manufacture. In June, Sandoz launched *Glatopa* the first generic competitor to Copaxone® 20 mg in the US. And in September in the US, Sandoz also launched *Zarxio,* which is the first biosimilar approved by the US Food and Drug Administration (FDA) under new regulations.

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Constant currencies change
	$ m	$ m	%	%
Retail Generics	7,199	7,933	(9)	2
Biopharmaceuticals & Oncology Injectables	1,378	1,094	26	39
Anti-Infectives	580	535	9	18
Total	**9,157**	**9,562**	**(4)**	**7**

Retail Generics

In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals. This franchise includes the specialty areas of dermatology, respiratory and ophthalmics, as well as finished dosage forms of anti-infective products sold under the Sandoz name. Retail Generics sales worldwide were $7.2 billion (9%, +2% cc). New product launches included US-authorized generics of our Pharmaceuticals Division's *Exelon Patch* and *Exforge*, as well as bivalirudin, an injectable anticoagulant.

Biopharmaceuticals and Oncology Injectables

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- and biotechnology-based products known as biosimilars, as well as *Glatopa*. Sandoz also provides biotechnology manufacturing services to other companies. Sales of biopharmaceuticals rose 25% (+39% cc) to $772 million. Sandoz further strengthened its leadership in biosimilars in 2015 with the US approval of *Zarxio* (filgrastim), used to fight infection in cancer patients receiving chemotherapy.

Sandoz is the global market leader in biosimilars with three products that continue to see strong growth in their respective categories: *Omnitrope*, a human growth hormone; *Binocrit,* an erythropoiesis-stimulating agent; and filgrastim under the brand names *Zarzio* outside the US and *Zarxio* in the US. We continued in 2015 to build our portfolio of biosimilars. The FDA and European Medicines Agency confirmed acceptance of our applications for etanercept, a proposed biosimilar to Amgen's Enbrel®, which treats autoimmune diseases such as rheumatoid arthritis and psoriasis. The FDA also accepted our applications for pegfilgrastim, a proposed biosimilar to Amgen's Neulasta®, used to reduce the chance of infection in cancer patients receiving chemotherapy. Sandoz has five biosimilars in Phase III development or registration preparation.

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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.

Anti-Infectives

Sandoz manufactures pharmaceutical ingredients and intermediates mainly antibiotics for sale under the Sandoz name and to third-party customers. Total Anti-Infectives sales were $1.4 billion, up 9% (cc) driven by a strong flu season and restored production capacity after 2014 quality upgrades. Sales of finished dosage forms sold under the Sandoz name reached $860 million. Anti-Infectives sold to third parties for sale under their own name reached $580 million.

Operating Income from Continuing Operations

Operating income from continuing operations was $9.0 billion (19%, 2% cc), mainly due to amortization of the new oncology assets in Pharmaceuticals. The current year includes an exceptional expense of $400 million for a settlement of the specialty pharmacies case in the Southern District of New York, whereas the prior-year benefitted from a one-time commercial settlement gain of $302 million and $248 million gain from selling a Novartis Venture Fund investment. The negative currency impact of 17 percentage points was mainly due to the strong $ versus the euro, Japanese yen and emerging market currencies. Operating income margin in constant currencies decreased 1.4 percentage points; currency had a negative impact of 1.7 percentage points resulting in a net decrease of 3.1 percentage points to 18.2 percent of net sales.

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

	Year ended Dec 31, 2015	% of net sales	Year ended Dec 31, 2014	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Pharmaceuticals	**7,597**	**25.0**	**8,471**	**26.6**	**(10)**	**5**
Alcon	**794**	**8.1**	**1,597**	**14.8**	**(50)**	**(20)**
Sandoz	**1,005**	**11.0**	**1,088**	**11.4**	**(8)**	**1**
Corporate	(419)		(67)		nm	nm
Operating income from continuing operations	**8,977**	**18.2**	**11,089**	**21.3**	**(19)**	**(2)**

nm = not meaningful

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Core Operating Income key figures[1]

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core gross profit from continuing operations	**36,900**	**38,821**	**(5)**	**5**
Marketing & Sales	(11,729)	(12,355)	5	(5)
Research & Development	(8,738)	(8,723)	0	(6)
General & Administration	(2,389)	(2,552)	6	0
Other income	823	563	46	59
Other expense	(1,077)	(1,281)	16	7
Core operating income from continuing operations	**13,790**	**14,473**	**(5)**	**10**
as % of net sales	*27.9%*	*27.7%*		

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

The adjustments made to operating income to arrive at core operating income from continuing operations amounted to $4.8 billion (2014: $3.4 billion). The increase was mainly driven by higher amortization of the new oncology assets in Pharmaceuticals, higher legal settlement expense and higher acquisition-related expense, whereas 2014 included a commercial settlement gain of $302 million, partially offset by the provision of $204 million for the US healthcare reform fee.

Excluding these items, core operating income from continuing operations decreased 5% (+10% cc) to $13.8 billion. Core operating income margin in constant currencies increased 1.3 percentage points mainly due to higher sales and productivity initiatives; currency had a negative impact of 1.1 percentage points, resulting in a margin of 27.9% of net sales, compared to 27.7% in 2014.

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

	Year ended Dec 31, 2015	% of net sales	Year ended Dec 31, 2014	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Pharmaceuticals	**9,420**	**30.9**	**9,514**	**29.9**	**(1)**	**14**
Alcon	**3,063**	**31.2**	**3,811**	**35.2**	**(20)**	**(7)**
Sandoz	**1,659**	**18.1**	**1,571**	**16.4**	**6**	**17**
Corporate	(352)		(423)		17	11
Core operating income from continuing operations	**13,790**	**27.9**	**14,473**	**27.7**	**(5)**	**10**

Pharmaceuticals

Operating income was $7.6 billion (10%, +5% cc) and included the effects of the acquisition of GSK's oncology portfolio, among other exceptional items.

Core operating income, which excludes certain exceptional items, was $9.4 billion (1%, +14% cc), helped by our ongoing efforts to improve productivity and control costs. Core operating income margin improved by 2.4 percentage points in constant currencies. However, that

was offset by 1.4 percentage points of negative impact from currency exchange rates, yielding a core margin of 30.9% of net sales.

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Research and development

The following table provides an overview on the reported and core Research and Development expense of the Pharmaceuticals Division:

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Research and Exploratory Development	(2,565)	(2,724)	6	3
Confirmatory Development	(4,667)	(4,607)	(1)	(7)
Total Pharmaceuticals Division Research and Development expense	**(7,232)**	**(7,331)**	**1**	**(3)**
as % of Pharmaceuticals net sales to third parties	*23.8%*	*23.1%*		
Core Research and Exploratory Development[1]	(2,493)	(2,654)	6	3
Core Confirmatory Development[1]	(4,560)	(4,343)	(5)	(11)
Total Core Pharmaceuticals Division Research and Development expense	**(7,053)**	**(6,997)**	**(1)**	**(5)**
as % of Pharmaceuticals net sales to third parties	*23.2%*	*22.0%*		

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

Pharmaceuticals Division Research and Exploratory Development expenditure amounted to $7.2 billion in 2015, a decrease of 1% (3% cc) compared to 2014. Confirmatory Development expenditures increased by 1% (7% cc) to $4.7 billion, compared to $4.6 billion in 2014, mainly driven by the additional development expense for the new oncology assets acquired from GSK.

Core R&D expense in the Pharmaceuticals Division as percent of sales decreased by 0.1 percentage points in constant currencies, which was offset by negative currency movements of 1.3 percentage points mainly from the sales base, as the Core R&D expenses are primarily denominated in US dollars and Swiss francs, which resulted in a net increase of 1.2 percentage points to 23.2% of net sales.

Alcon

Operating income was $0.8 billion (50%, 20% cc).

Core operating income, which excludes certain items, was $3.1 billion (20%, 7% cc), impacted by lower sales, higher spending (primarily on marketing and sales), investments in product development, and increased provisions for bad debt in Asia. Core operating income margin declined 2.1 percentage points in constant currencies and currency exchange rates had a negative impact of 1.9 percentage points, yielding a core margin of 31.2% of net sales.

Sandoz

Operating income was $1.0 billion (8%, +1% cc).

Core operating income, which excludes certain exceptional items, increased 6% (+17% cc) to $1.7 billion. Core operating income margin increased 1.5 percentage points in constant currencies and currency exchange rates had a positive impact of 0.2 percentage points, yielding a core margin of 18.1% of net sales.

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Corporate Income and Expense, Net

Corporate income and expense amounted to a net expense of $419 million in 2015 compared to a net expense of $67 million in the prior year. The increased expense was mainly due to the $302 million commercial settlement gain and a $248 million gain from selling Novartis Venture Fund investments recorded in 2014, partially offset by the gain on the sale of real estate in Switzerland of $54 million, lower share-based compensation accruals and lower provisions in the captive insurance companies in 2015.

Non-Operating Income and Expense

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

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Operating income from continuing operations	**8,977**	**11,089**	**(19)**	**(2)**
Income from associated companies	266	1,918	(86)	(86)
Interest expense	(655)	(704)	7	2
Other financial income and expense	(454)	(31)	nm	nm
Income before taxes from continuing operations	**8,134**	**12,272**	**(34)**	**(17)**
Taxes	(1,106)	(1,545)	28	10
Net income from continuing operations	**7,028**	**10,727**	**(34)**	**(18)**
Net income/loss from discontinued operations	10,766	(447)	nm	nm
Net income	**17,794**	**10,280**	**73**	**91**
Basic EPS ($) from continuing operations	**2.92**	**4.39**	**(33)**	**(17)**
Basic EPS ($) from discontinued operations	4.48	(0.18)	nm	nm
Total basic EPS ($)	**7.40**	**4.21**	**76**	**94**

nm = not meaningful

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

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core operating income from continuing operations	**13,790**	**14,473**	**(5)**	**10**
Income from associated companies	981	943	4	4
Interest expense	(655)	(704)	7	2
Other financial income and expense	(24)	(31)	23	nm
Core income before taxes from continuing operations	**14,092**	**14,681**	**(4)**	**10**
Taxes	(2,051)	(2,028)	(1)	(16)
Core net income from continuing operations	**12,041**	**12,653**	**(5)**	**9**
Core net income/loss from discontinued operations	(256)	102	nm	nm
Core net income	**11,785**	**12,755**	**(8)**	**6**
Core basic EPS ($) from continuing operations	**5.01**	**5.19**	**(3)**	**10**
Core basic EPS ($) from discontinued operations	(0.11)	0.04	nm	nm
Core basic EPS ($)	**4.90**	**5.23**	**(6)**	**7**

nm = not meaningful

Income from associated companies

Income from associated companies from continuing operations amounted to $266 million in 2015, compared to $1.9 billion in 2014. The prior-year benefited from a pre-tax gain of $0.8 billion recognized on the sale of the shares of Idenix to Merck, a gain of $0.4 billion from the divestment of the shareholding in LTS and from the gain of $64 million recorded on the Novartis Venture Funds investments.

In addition, the estimated income from Roche Holding AG declined from $599 million in the prior-year period to $343 million in 2014, due to an adjustment of $157 million recognized in the first quarter of 2015 when Roche published full year results, as well as a lower estimated income contribution from Roche for 2015 due to an announced restructuring.

The estimated share in net results from the GSK Consumer Healthcare joint venture amounted to a loss of $17 million, as income from operations was more than offset by integration charges. This estimate will be adjusted based on actual results in the first quarter of 2016. In addition, in 2015, we finalized the purchase price allocation for the investment in the GSK Consumer Healthcare joint venture which is accounted for as associated company and recognized amortization of purchase price adjustments of $62 million, resulting in a total estimated loss of $79 million for our share in the net results from the GSK Consumer Healthcare joint venture for the year.

Core income from associated companies increased to $981 million compared to $943 million in 2014. Our estimated share in core results from the consumer healthcare joint venture with GSK, which amounted to $213 million in 2015, was offset by decreases in our estimated share of core results from Roche (from $856 million to $766 million) and prior-year income from associated companies of the Novartis Venture Fund.

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Interest Expense and other financial income and expense

Interest expense from continuing operations decreased by 7% (2% cc) to $655 million from $704 million in the prior year.

Other financial income and expense amounted to an expense of $454 million compared to $31 million in the prior-year period mainly on account of the exceptional charges of $410 million related to Venezuela due to foreign exchange losses of $211 million and monetary losses from hyperinflation accounting of $72 million and a loss of $127 million on the sale of PDVSA bonds received to settle a portion of intra-group payables.

Core other financial income and expense, which exclude the exceptional charges of $410 million related to Venezuela, amounted to a net expense of $24 million, compared to $31 million in 2014.

Taxes

The tax rate for continuing operations (taxes as percentage of pre-tax income) in 2015 increased to 13.6% from 12.6% in the prior year, as a result of a change in profit mix from lower to higher tax jurisdictions.

The core tax rate from continuing operations (core tax as a percentage of core pre-tax income) increased to 14.6% from 13.8% in 2014, mainly as a result of a change in profit mix from lower to higher tax jurisdictions.

Net Income

Net income from continuing operations of $7.0 billion was down 34% (18% cc) declining more than operating income mainly due to the exceptional charges related to Venezuela in the current year and the prior-year gains of $0.8 billion from the sale of Idenix shares and $0.4 billion from the sale of LTS shares.

Core net income from continuing operations of $12.0 billion was down 5% (+9% cc), in line with core operating income.

EPS

Basic earnings per share (EPS) from continuing operations was $2.92 per share, down 33% (17% cc), declining less than net income from continuing operations due to the lower number of outstanding shares.

Core basic EPS from continuing operations was $5.01 (3%, +10% cc), growing ahead of core net income due to lower average outstanding shares and lower minority interests.

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Discontinued Operations

	Year ended Dec 31, 2015	Year ended Dec 31, 2014
	$ m	$ m
Net sales to third parties from discontinued operations	**601**	**5,816**
Operating income/loss from discontinued operations	**12,477**	**(353)**
Net income/loss from discontinued operations	**10,766**	**(447)**
Attributable to:		
Shareholders of Novartis AG	*10,758*	*(444)*
Non-controlling interests	*8*	*(3)*
Basic earnings per share ($) from discontinued operations	**4.48**	**(0.18)**
Free cash flow from discontinued operations	**(230)**	**(172)**

Operational results for discontinued operations in 2015 include the results from the Vaccines influenza business, prior to its divestment to CSL Limited on July 31, 2015, as well as results from the Vaccines non-influenza business and OTC until March 2, 2015. Operational results from the Animal Health business, which was divested on January 1, 2015 include only the divestment gain. The prior year included the results of all divested units during the full year.

Discontinued operations also include the exceptional pre-tax gains of $12.7 billion from the divestment of Animal Health ($4.6 billion) and the transactions with GSK ($2.8 billion for the Vaccines non-influenza business and $5.9 billion arising from the contribution of Novartis OTC into the GSK Consumer Healthcare joint venture). In addition, the GSK transactions resulted in $0.6 billion of additional transaction-related costs that were expensed.

Net sales to third parties of the discontinued operations in 2015 amounted to $0.6 billion compared to $5.8 billion in 2014.

Operating income from discontinued operations in 2015 amounted to an income of $12.5 billion which was mainly driven by the exceptional pre-tax gains from the portfolio transformation. Excluding the divestment gains, the remaining operating loss from discontinued operations was $0.2 billion, representing the operating performance of the Vaccines influenza business up to July 31, 2015 as well as the Vaccines non-influenza business and OTC until their respective divestment dates, and is net of the partial reversal of $0.1 billion of the impairment of the assets of Vaccines influenza business recorded in 2014.

The prior year operating loss of $353 million included an exceptional impairment charge of $1.1 billion for the Vaccines influenza business which was partially offset by an exceptional pre-tax gain of $0.9 billion from the divestment of our blood transfusion diagnostics unit.

Net income from discontinued operations amounted to $10.8 billion in 2015 compared to a net loss $447 million in 2014. For more information on discontinued operations see " Factors Affecting Comparability of Year-On-Year Results of Operations", below and "Item 18. Financial Statements Note 30".

Total Group

For the total Group, net income amounted to $17.8 billion compared to $10.3 billion in 2014, impacted by the exceptional divestment gains included in the net income from the discontinued operations. Basic earnings per share increased to $7.40 from $4.21.

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2014 Compared to 2013

Group Overview

Following the announcement of the transactions with GlaxoSmithKline plc (GSK) and Eli Lilly and Company (Lilly) on April 22, 2014 (and the subsequent announcement of the transaction with CSL Limited (CSL)), in which we agreed to divest our Vaccines, OTC and Animal Health businesses to those companies, the businesses to be divested were accounted for as discontinued operations and were not included in our results from continuing operations for 2013 and 2014. In addition, on January 9, 2014, Novartis completed the divestment to Grifols S.A. of our former blood transfusion diagnostics unit, which had been included in our former Vaccines and Diagnostics Division. The results of this divested business were also accounted for as discontinued operations and not included in our results from continuing operations. See " Factors Affecting Comparability Of Year-On-Year Results Of Operations."

Key figures

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales to third parties from continuing operations	**52,180**	**51,869**	**1**	**3**
Sales to discontinued segments	239	221	8	8
Net sales from continuing operations	**52,419**	**52,090**	**1**	**3**
Other revenues	1,215	626	94	94
Cost of goods sold	(17,345)	(16,579)	(5)	(6)
Gross profit from continuing operations	**36,289**	**36,137**	**0**	**3**
Marketing & Sales	(12,377)	(12,638)	2	0
Research & Development	(9,086)	(9,071)	0	0
General & Administration	(2,616)	(2,603)	0	(1)
Other income	1,391	1,205	15	15
Other expense	(2,512)	(2,047)	(23)	(23)
Operating income from continuing operations	**11,089**	**10,983**	**1**	**7**
Return on net sales (%)	21.3	21.2		
Income from associated companies	1,918	599	220	221
Interest expense	(704)	(683)	(3)	(6)
Other financial income and expense	(31)	(92)	66	31
Income before taxes from continuing operations	**12,272**	**10,807**	**14**	**19**
Taxes	(1,545)	(1,498)	(3)	(8)
Net income from continuing operations	**10,727**	**9,309**	**15**	**21**
Net income/loss from discontinued operations	(447)	(17)	nm	nm
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 earnings per share ($) from continuing operations	**4.39**	**3.76**	**17**	**22**
Basic earnings per share ($) from discontinued operations	(0.18)	0.00	nm	nm
Total basic earnings per share ($)	**4.21**	**3.76**	**12**	**18**

Free cash flow from continuing operations	**10,934**	**9,521**	**15**
Free cash flow	**10,762**	**9,945**	**8**

nm = not meaningful

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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 net sales from continuing operations of $52.2 billion (+1%, +3% cc). Operating income from continuing operations amounted to $11.1 billion (+1%, +7% cc). Operating income margin was 21.3% of net sales. Net income from continuing operations rose 15% (+21% cc) to $10.7 billion. Earnings per share (EPS) from continuing operations rose 17% (+22% cc) to $4.39. In 2014, free cash flow from continuing operations increased by $1.4 billion to $10.9 billion, mainly due to higher cash flows from operating activities.

In addition, to help investors' understanding of the performance 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. In 2014, our core operating income from continuing operations increased 2% (+7% cc) to $14.5 billion. Core operating income margin increased 0.3 percentage points to 27.7% of net sales, as our efforts to enhance productivity helped to offset 0.8 percentage points of negative impact from changing currency exchange rates. Core net income from continuing operations was $12.7 billion, up 3% (+8% cc), and core basic earnings per share from continuing operations rose 4% (+9% cc) to $5.19.

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 36% 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.

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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 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 total 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

	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**
Net sales to third parties from continuing operations	**52,180**	**51,869**	**1**	**3**

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.

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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.

TOP 20 PHARMACEUTICALS DIVISION PRODUCT NET SALES 2014

			US		Rest of world		Total		
Brands	**Business Franchise**	**Indication**	**$ m**	**% change in constant currencies**	**$ m**	**% change in constant currencies**	**$ m**	**% change in $**	**% change in constant currencies**
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

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

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Constant currencies change
	$ m	$ m	%	%
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 currencies 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.

Operating Income from Continuing Operations

Operating income from continuing operations amounted to $11.1 billion (+1%, +7% cc). 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 21.3% of net sales, which was 0.1 percentage points higher than the prior year. A 0.9 percentage point increase (in constant currencies) from the prior year, was offset by a negative currency impact of 0.8 percentage points.

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	(67)		(653)		nm	nm
Operating income from continuing operations	**11,089**	**21.3**	**10,983**	**21.2**	**1**	**7**

nm = not meaningful

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Core Operating Income key figures[1]

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core gross profit from continuing operations	**38,821**	**38,792**	**0**	**3**
Marketing & Sales	(12,355)	(12,611)	2	0
Research & Development	(8,723)	(8,885)	2	2
General & Administration	(2,552)	(2,578)	1	0
Other income	563	648	(13)	(13)
Other expense	(1,281)	(1,159)	(11)	(10)
Core operating income from continuing operations	**14,473**	**14,207**	**2**	**7**
as % of net sales	*27.7%*	*27.4%*		

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

The adjustments made to operating income to arrive at core operating income from continuing operations amounted to $3.4 billion (2013: $3.2 billion). These adjustments include amortization of intangible assets of $2.7 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 $0.4 billion and net restructuring charges of $0.7 billion. These were partly offset by a $302 million commercial settlement gain; and a $248 million gain from selling a Novartis Venture Fund investment.

Excluding these items, core operating income from continuing operations increased 2% (+7% cc) to $14.5 billion. Core operating income margin in constant currencies increased 1.1 percentage points; currency had a negative impact of 0.8 percentage points, resulting in a net increase of 0.3 percentage points to 27.7% of net sales. Additional comments on the changes in the core operating income by division, see " Non IFRS Measures as Defined by Novartis".

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	(423)		(551)		23	25
Core operating income from continuing operations	**14,473**	**27.7**	**14,207**	**27.4**	**2**	**7**

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.

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Research and development

Research and development for continuing operations totaled $9.1 billion, in line with the prior-year level. As shown in the following table, in the Pharmaceuticals Division, Research and Exploratory Development expenditure amounted to $2.7 billion in 2014, up by 2% from 2013, and Confirmatory Development expenditures amounted to $4.6 billion, practically unchanged from 2013.

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Research and Exploratory Development	(2,724)	(2,664)	(2)	(2)
Confirmatory Development	(4,607)	(4,578)	(1)	(1)
Total Pharmaceuticals Division Research and Development expense	**(7,331)**	**(7,242)**	**(1)**	**(1)**
as % of Pharmaceuticals net sales to third parties	23.1	22.5		
Core Research and Exploratory Development[1]	(2,654)	(2,611)	(2)	(1)
Core Confirmatory Development[1]	(4,343)	(4,550)	5	4
Total Core Pharmaceuticals Division Research and Development expense	**(6,997)**	**(7,161)**	**2**	**2**
as % of Pharmaceuticals net sales to third parties	*22.0%*	*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.

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Non-Operating Income and 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	%	%
Operating income from continuing operations	**11,089**	**10,983**	**1**	**7**
Income from associated companies	1,918	599	220	221
Interest expense	(704)	(683)	(3)	(6)
Other financial income and expense	(31)	(92)	66	31
Income before taxes from continuing operations	**12,272**	**10,807**	**14**	**19**
Taxes	(1,545)	(1,498)	(3)	(8)
Net income from continuing operations	**10,727**	**9,309**	**15**	**21**
Net loss from discontinued operations	(447)	(17)	nm	nm
Net income	**10,280**	**9,292**	**11**	**17**
Basic EPS ($) from continuing operations	**4.39**	**3.76**	**17**	**22**
Basic EPS ($) from discontinued operations	(0.18)	0.00	nm	nm
Total basic EPS ($)	**4.21**	**3.76**	**12**	**18**

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

	Year ended Dec 31, 2014	Year ended Dec 31, 2013	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core operating income from continuing operations	**14,473**	**14,207**	**2**	**7**
Income from associated companies	943	876	8	8
Interest expense	(704)	(683)	(3)	(6)
Other financial income and expense	(31)	(48)	35	31
Core income before taxes from continuing operations	**14,681**	**14,352**	**2**	**7**
Taxes	(2,028)	(2,057)	1	(3)
Core net income from continuing operations	**12,653**	**12,295**	**3**	**8**
Core net income from discontinued operations	102	238	(57)	(34)
Core net income	**12,755**	**12,533**	**2**	**7**
Core basic EPS ($) from continuing operations	**5.19**	**4.99**	**4**	**9**
Core basic EPS ($) from discontinued operations	0.04	0.10	nm	nm
Core basic EPS ($)	**5.23**	**5.09**	**3**	**8**

nm = not meaningful

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Income from associated companies

Income from associated companies from continuing operations amounted to $1.9 billion in 2014, compared to $599 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 from continuing operations increased to $943 million from $876 million in the prior-year period.

Interest Expense and other financial income and expense

Interest expense from continuing operations 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 tax rate for continuing operations in the full year of 2014 decreased to 12.6% from 13.9% in the prior year, mainly due to the impact of taxes on the various exceptional gains which occurred during the year.

The core tax rate from continuing operations decreased slightly to 13.8% from 14.3% in 2013.

Net Income

Net income from continuing operations of $10.7 billion was up 15% (+21% cc), growing ahead of operating income mainly due to higher income from 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.

Core net income from continuing operations of $12.7 billion was up 3% (+8% cc), growing slightly ahead of core operating income (2%, 7% cc).

EPS

Earnings per share (EPS) from continuing operations was $4.39 per share, up 17% (+22% cc), growing ahead of net income due to lower average outstanding shares and lower minority interests.

Core EPS from continuing operations was $5.19 (+4%, +9% cc), growing ahead of core net income due to lower average outstanding shares and lower minority interests.

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Discontinued Operations

	Year ended Dec 31, 2014	Year ended Dec 31, 2013
	$ m	$ m
Net sales to third parties from discontinued operations	**5,816**	**6,051**
Operating loss from discontinued operations	**(353)**	**(73)**
Net loss from discontinued operations	**(447)**	**(17)**
Attributable to:		
Shareholders of Novartis AG	*(444)*	*(14)*
Non-controlling interests	*(3)*	*(3)*
Basic earnings per share ($) from discontinued operations	**(0.18)**	**0**
Free cash flow from discontinued operations	**(172)**	**424**

Net sales to third parties of the discontinued operations in 2014 declined 4% (1% in cc) to $5.8 billion from $6.1 billion in 2013.

Operating loss from discontinued operations amounted to $353 million in 2014 compared to $73 million in 2013. The operating loss of $353 million in 2014 included an exceptional impairment charge of $1.1 billion for the influenza vaccines business which was partially offset by an exceptional pre-tax gain of $0.9 billion from the divestment of our blood transfusion diagnostics unit.

Net loss from discontinued operations amounted to $447 million in 2014 compared to a net loss $17 million in 2013.

Total Group

For the total Group, net income amounted to $10.3 billion compared to $9.3 billion in 2013., impacted by the exceptional divestment gains included in the net income. Basic earnings per share increased to $4.21 from $3.76.

FACTORS AFFECTING COMPARABILITY OF YEAR-ON-YEAR RESULTS OF OPERATIONS

Significant transactions in 2015

The comparability of the year-on-year results of our operations for the total Group can be significantly affected by acquisitions and divestments. The transactions of significance during 2015 and 2014 are mentioned below.

Acquisitions and Divestments in 2015

PORTFOLIO TRANSFORMATION TRANSACTIONS

Transaction with Eli Lilly and Company

On January 1, 2015, Novartis closed its transaction with Eli Lilly and Company, USA (Lilly) announced in April 2014 to divest its Animal Health business for $5.4 billion in cash. This resulted in a pre-tax gain of $4.6 billion which is recorded in operating income from discontinued operations.

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Transactions with GlaxoSmithKline plc

On March 2, 2015, Novartis closed its transactions with GlaxoSmithKline plc, Great Britain (GSK) announced in April 2014 with the following consequences:

Pharmaceuticals Acquisition of GSK oncology products

Novartis acquired GSK's oncology products and certain related assets for an aggregate cash consideration of $16.0 billion. Up to $1.5 billion of this cash consideration at the acquisition date is contingent on certain development milestones. The fair value of this potentially refundable consideration is $0.1 billion. In addition, under the terms of the agreement, Novartis is 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 12.5 years from the acquisition closing date. The purchase price allocation of the fair value of the consideration of $15.9 billion resulted in net identified assets of $13.5 billion and goodwill of $2.4 billion. Since the acquisition the business generated net sales of $1.8 billion. Management estimates net sales for the entire year 2015 would have amounted to $2.1 billion had the Oncology products been acquired at the beginning of the 2015 reporting period. The net results from operations on a reported basis since the acquisition date were not significant, mainly due to amortization of intangible assets.

Vaccines Divestment

Novartis has divested its Vaccines business (excluding its Vaccines influenza business) to GSK for up to $7.1 billion, plus royalties. The $7.1 billion consists of $5.25 billion paid at closing and up to $1.8 billion in future milestone payments. The fair value of the contingent future milestones and royalties is $1.0 billion, resulting in a fair value of consideration received of $6.25 billion. Included in this amount is a $450 million milestone payment received in late March 2015. The sale of this business resulted in a pre-tax gain of $2.8 billion which is recorded in operating income from discontinued operations.

Novartis's Vaccines influenza business is excluded from the GSK Vaccines business acquisition. However, GSK entered into a future option arrangement with Novartis in relation to the Vaccines influenza business, pursuant to which Novartis could have unilaterally required GSK to acquire the entire or certain parts of its Vaccines influenza business for consideration of up to $250 million (the Influenza Put Option) if the divestment to CSL Limited, Australia (CSL), discussed below, had not been completed. The option period was 18 months from the closing date of the GSK transaction, but terminated with the sale of the Vaccines influenza business to CSL on July 31, 2015. Novartis paid GSK a fee of $5 million in consideration for the grant of the Influenza Put Option.

Consumer Health Combination of Novartis OTC with GSK Consumer Healthcare in a joint venture

Novartis and GSK agreed to create a combined consumer healthcare business through a joint venture between Novartis OTC and GSK Consumer Healthcare. On March 2, 2015, a new entity was formed via contribution of businesses from both Novartis and GSK. Novartis has a 36.5% interest in the newly created entity. Novartis has valued the contribution of 63.5% of its OTC Division in exchange for 36.5% of the GSK Consumer Healthcare business at fair value.

Based on the estimates of the fair values exchanged, an investment in an associated company of $7.6 billion was recorded. The resulting pre-tax gain, net of transaction-related costs, of $5.9 billion is recorded in operating income from discontinued operations.

Novartis has four of eleven seats on the joint venture entity's Board of Directors. Furthermore, Novartis has customary minority rights and also exit rights at a pre-defined, market-based pricing mechanism.

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The investment is accounted for using the equity method of accounting using estimated results for the last quarter of the year. Any differences between this estimate and actual results, when available, will be adjusted in the Group's 2016 consolidated financial statements.

Additional GSK related cost

The GSK transaction resulted in $0.6 billion of additional transaction-related costs that were expensed.

Transaction with CSL

On October 26, 2014, Novartis entered into an agreement with CSL to sell its Vaccines influenza business to CSL for $275 million. Entering into the separate divestment agreement with CSL resulted in the Vaccines influenza business being classified as a separate disposal group consisting of a group of cash generating units within the Vaccines Division, requiring the performance of a separate valuation of the Vaccines influenza business net assets. This triggered the recognition of an exceptional impairment charge in 2014 of $1.1 billion, as the estimated net book value of the Vaccines influenza business net assets was above the $275 million consideration.

The transaction with CSL was completed on July 31, 2015, resulting in a partial reversal of the impairment recorded in 2014 in the amount of $0.1 billion, which is included in operating income from discontinued operations.

Other significant Transactions in 2015

Pharmaceuticals Acquisition of Spinifex Pharmaceuticals, Inc.

On June 29, 2015 Novartis entered into an agreement to acquire Spinifex Pharmaceuticals, Inc. (Spinifex), a US and Australian-based, privately held development stage company, focused on developing a peripheral approach to treat neuropathic pain. The transaction closed on July 24, 2015, and the total purchase consideration was $312 million. The amount consisted of an initial cash payment of $196 million and the net present value of the contingent consideration of $116 million due to previous Spinifex shareholders, which they are eligible to receive upon achievement of specified development and commercialization milestones. The purchase price allocation resulted in net identifiable assets of $263 million and goodwill of $49 million. Results of operations since the date of acquisition were not material.

Pharmaceuticals Acquisition Admune Therapeutics LLC.

On October 16, 2015, Novartis acquired Admune Therapeutics LLC (Admune), a US-based, privately held company, broadening Novartis' pipeline of cancer immunotherapies. The total purchase consideration amounted to $258 million. This amount consists of an initial cash payment of $140 million and the net present value of the contingent consideration of $118 million due to Admune's previous owners, which they are eligible to receive upon the achievement of specified development and commercialization milestones. The purchase price allocation resulted in net identifiable assets of $258 million. No goodwill was recognized. Results of operations since the date of acquisition were not material.

Acquisitions and Divestments in 2014

Vaccines Divestment of blood transfusion diagnostics unit

On January 9, 2014, Novartis completed the divestment of its blood transfusion diagnostics unit to the Spanish company Grifols S.A. for $1.7 billion in cash. The pre-tax gain on this transaction was approximately $0.9 billion and was recorded in operating income from discontinued operations.

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Pharmaceuticals Acquisition of CoStim Pharmaceuticals, Inc.

On February 17, 2014, Novartis acquired all of the outstanding shares of CoStim Pharmaceuticals Inc., a Cambridge, Massachusetts, US-based, privately held biotechnology company focused on harnessing the immune system to eliminate immune-blocking signals from cancer, for a total purchase consideration of $248 million (excluding cash acquired). This amount consists of an initial cash payment and the net present value of contingent consideration of $153 million due to previous CoStim shareholders, which they are eligible to receive upon the achievement of specified development and commercialization milestones. The purchase price allocation resulted in net identified assets of $152 million (excluding cash acquired) and goodwill of $96 million. Results of operations since the date of acquisition were not material.

Pharmaceuticals Divestment of Idenix Pharmaceuticals, Inc. (Idenix) Shareholding

On August 5, 2014, Merck & Co., USA completed a tender offer for Idenix. As a result, Novartis divested its 22% shareholding in Idenix and realized a gain of approximately $0.8 billion which was recorded in income from associated companies.

Alcon Acquisition of WaveTec Vision Systems, Inc. (WaveTec)

On October 16, 2014, Alcon acquired all of the outstanding shares of WaveTec, a privately held company, for $350 million in cash. The purchase price allocation resulted in net identified assets of $180 million and goodwill of $170 million. Results of operations since the date of acquisition were not material.

Corporate Divestment of LTS Lohmann Therapie-Systeme AG (LTS) Shareholding

On November 5, 2014, Novartis divested its 43% shareholding in LTS and realized a gain of approximately $0.4 billion which was recorded in income from associated companies.

Classification as continuing operations and discontinued operations

Following the April 22, 2014 announcement of the portfolio transformation transactions with Lilly and GSK, as described above, Novartis reported the Group's financial statements for the current and prior years as "continuing operations" and "discontinued operations".

Continuing operations comprise the activities of the Pharmaceuticals, Alcon and Sandoz Divisions and the continuing Corporate activities. Continuing operations also include the results from Oncology assets acquired from GSK and the estimated results from the 36.5% interest in the GSK/Novartis consumer healthcare joint venture for the period from March 2, 2015 to December 31, 2015 (the latter reported as part of income from associated companies).

Discontinued operations include in 2015 the operational results from the Vaccines influenza business, prior to its divestment to CSL Limited on July 31, 2015, as well as results from the Vaccines non-influenza business and OTC business until March 2, 2015. Operational results from the Animal Health business, which was divested on January 1, 2015, include only the divestment gain.

Discontinued operations in 2015 also include the exceptional pre-tax gain of $12.7 billion from the divestment of Animal Health ($4.6 billion) and the transactions with GSK ($2.8 billion for the Vaccines non-influenza business and $5.9 billion arising from the contribution of Novartis OTC into the GSK Consumer Healthcare joint venture). In addition the GSK transactions resulted in $0.6 billion of additional transaction-related expenses reported in Corporate discontinued operations.

In 2014, discontinued operations include the results of the Vaccines influenza and non-influenza business, OTC and Animal Health for the full year. Results also included an exceptional impairment

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charge of $1.1 billion for the Vaccines influenza business, which was reduced by $0.1 billion in 2015 upon closing of the CSL transaction and an exceptional pre-tax gain of $0.9 billion arising from the $1.7 billion divestment of the blood transfusion diagnostics unit to Grifols S.A., completed on January 9, 2014.

Excluded from discontinued operations are certain intellectual property rights and related other revenues of the Vaccines Division, which are retained by Novartis and are now reported under Corporate activities.

As required by IFRS, results of the discontinued operations exclude any further depreciation and amortization related to discontinued operations from the date of the portfolio transformation announcement of April 22, 2014.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are set out in "Item 18. Financial Statements Note 1", which are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

Given the uncertainties inherent in our business activities, we must make certain estimates and assumptions that require difficult, subjective and complex judgments. Because of uncertainties inherent in such judgments, actual outcomes and results may differ from our assumptions and estimates, which could materially affect the Group's consolidated financial statements. Application of the following accounting policies requires certain assumptions and estimates that have the potential for the most significant impact on our consolidated financial statements.

Deductions from Revenues

As is typical in the pharmaceuticals industry, our gross sales are subject to various deductions which are composed primarily of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales.

The following summarizes the nature of some of these deductions and how the deduction is estimated. After recording these, net sales represent our best estimate of the cash that we expect to ultimately collect. The US market has the most complex arrangements related to revenue deductions.

United States specific healthcare plans and program rebates

The United States Medicaid Drug Rebate Program is administered by State governments using State and Federal funds to provide assistance to certain vulnerable and needy individuals and families. Calculating the rebates to be paid related to this Program involves interpreting relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, product price increases and the mix of contracts and specific terms in the individual State agreements. These provisions are adjusted based on established processes and experiences from filing data with individual States.

The United States Federal Medicare Program, which funds healthcare benefits to individuals age 65 or older, provides prescription drug benefits under Part D of the program. This benefit is provided through private prescription drug plans. Provisions for estimating Medicare Part D rebates are calculated based on the terms of individual plan agreements, product sales and population growth, product price increases and the mix of contracts, and are adjusted periodically.

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We offer rebates to key managed healthcare plans in an effort to sustain and increase sales of our products. These rebate programs provide payors a rebate after they have demonstrated they have met all terms and conditions set forth in their contract with us. These rebates are estimated based on the terms of individual agreements, historical experience and projected product growth rates. We adjust provisions related to these rebates periodically to reflect actual experience.

There is often a time lag of several months between us recording the revenue deductions and our final accounting for them.

Non-United States specific healthcare plans and program rebates

In certain countries other than the US, we provide rebates to governments and other entities. These rebates are often mandated by laws or government regulations.

In several countries we enter into innovative pay-for-performance arrangements with certain healthcare providers, especially in Europe and Australia. Under these agreements, we may be required to make refunds to the healthcare providers or to provide additional medicines free of charge if anticipated treatment outcomes do not meet predefined targets. Potential refunds and the delivery of additional medicines at no cost are estimated and recorded as a deduction of revenue at the time the related revenues are recorded. Estimates are based on historical experience and clinical data. In cases where historical experience and clinical data are not sufficient for a reliable estimation of the outcome, revenue recognition would be deferred until such history would be available. In addition, we offer global patient assistant programs.

There is often a time lag of several months between us recording the revenue deductions and our final accounting for them.

Non-healthcare plans and program rebates, returns and other deductions

Charge-backs occur where our subsidiaries have arrangements with indirect customers to sell products at prices that are lower than the price charged to wholesalers. A charge-back represents the difference between the invoice price to the wholesaler and the indirect customer's contract price. We account for vendor charge-backs by reducing revenue by an amount equal to our estimate of charge-backs attributable to a sale and they are generally settled within one to three months of incurring the liability. Provisions for estimated charge-backs are calculated using a combination of factors such as historical experience, product growth rates, payments, level of inventory in the distribution channel, the terms of individual agreements and our estimate of the claims processing time lag.

We offer rebates to purchasing organizations and other direct and indirect customers to sustain and increase market share for our products. Since rebates are contractually agreed upon, rebates are estimated based on the terms of the individual agreements, historical experience, and projected product growth rates.

When we sell a product providing a customer the right to return it, we record a provision for estimated sales returns based on our sales returns policy and historical rates. Other factors considered include actual product recalls, expected marketplace changes, the remaining shelf life of the product, and the expected entry of generic products. In 2015, sales returns amounted to approximately 1% of gross product sales. If sufficient experience is not available, sales are only recorded based on evidence of product consumption or when the right of return has expired.

We enter into distribution service agreements with major wholesalers, which provide a financial disincentive for the wholesalers to purchase product quantities in excess of current customer demand. Where possible, we adjust shipping patterns for our products to maintain wholesalers' inventories level consistent with underlying patient demand.

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We offer cash discounts to customers to encourage prompt payment. Cash discounts are estimated and accrued at the time of invoicing and deducted from revenue.

Following a decrease in the price of a product, we generally grant customers a "shelf stock adjustment" for a customer's existing inventory for the relevant product. Provisions for shelf stock adjustments, which are primarily relevant within the Sandoz Division, are determined at the time of the price decline or at the point of sale, if the impact of a price decline on the products sold can be reasonably estimated based on the customer's inventory levels of the relevant product.

Other sales discounts, such as consumer coupons and co-pay discount cards, are offered in some markets. The estimated amount of these discounts are recorded at the time of sale, or when the coupon is issued, and are estimated utilizing historical experience and the specific terms for each program. If a discount for a probable future transaction is offered as part of a sales transaction then an appropriate portion of revenue is deferred to cover this estimated obligation.

We adjust provisions for revenue deductions periodically to reflect actual experience. To evaluate the adequacy of provision balances, we use internal and external estimates of the level of inventory in the distribution channel, actual claims data received and the time lag for processing rebate claims. Management also estimates the level of inventory of the relevant product held by retailers and in transit. External data sources include reports of wholesalers and third-party market data purchased by Novartis.

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The following table shows the worldwide extent of our revenue deductions provisions and related payment experiences for the Pharmaceuticals, Alcon and Sandoz divisions:

PROVISIONS FOR REVENUE DEDUCTIONS

	Revenue deductions provisions at January 1	Effect of currency translation and business combinations	Payments/ utilizations	Income statement charge		Change in provisions offset against gross trade receivables	Revenue deductions provisions at December 31
				Adjustments of prior years	Current year		
	$ m	$ m	$ m	$ m	$ m	$ m	$ m
2015							
US-specific healthcare plans and program rebates	1,097		(2,823)	(90)	2,981		1,165
Non-US-specific healthcare plans and program rebates	1,015	(109)	(1,716)	(3)	1,846	(9)	1,024
Non-healthcare plans and program-related rebates, returns and other deductions	1,421	(69)	(10,679)	(124)	10,993	59	1,601
Total continuing operations 2015	**3,533**	**(178)**	**(15,218)**	**(217)**	**15,820**	**50**	**3,790**
2014							
US-specific healthcare plans and program rebates	1,376		(3,118)	(186)	3,025		1,097
Non-US-specific healthcare plans and program rebates	1,145	(124)	(1,743)	(19)	1,787	(31)	1,015
Non-healthcare plans and program-related rebates, returns and other deductions	1,427	(83)	(9,046)	(52)	9,564	(389)	1,421
Total continuing operations 2014	**3,948**	**(207)**	**(13,907)**	**(257)**	**14,376**	**(420)**	**3,533**
2013							
US-specific healthcare plans and program rebates	1,434		(2,990)	(74)	3,006		1,376
Non-US-specific healthcare plans and program rebates	942	10	(1,634)	(45)	1,935	(63)	1,145
Non-healthcare plans and program-related rebates, returns and other deductions	1,444	(10)	(7,745)	(34)	7,934	(162)	1,427
Total continuing operations 2013	**3,820**	**0**	**(12,369)**	**(153)**	**12,875**	**(225)**	**3,948**

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The table below shows the gross to net sales reconciliation for our Pharmaceuticals Division:

GROSS TO NET SALES RECONCILIATION

	Income statement charge			
	Charged through revenue deduction provisions	Charged directly without being recorded in revenue deduction provisions	Total	In % of gross sales
	$ m	$ m	$ m	
2015				
Pharmaceuticals gross sales subject to deductions			**37,853**	**100.0**
US-specific healthcare plans and program rebates	(1,422)		(1,422)	(3.8)
Non-US-specific healthcare plans and program rebates	(1,150)	(779)	(1,929)	(5.1)
Non-healthcare plans and program-related rebates, returns and other deductions	(2,241)	(1,816)	(4,057)	(10.7)
Total Pharmaceuticals gross to net sales adjustments	**(4,813)**	**(2,595)**	**(7,408)**	**(19.6)**
Pharmaceuticals net sales 2015			**30,445**	**80.4**
2014				
Pharmaceuticals gross sales subject to deductions			**39,529**	**100.0**
US-specific healthcare plans and program rebates	(1,800)		(1,800)	(4.6)
Non-US-specific healthcare plans and program rebates	(1,200)	(877)	(2,077)	(5.3)
Non-healthcare plans and program-related rebates, returns and other deductions	(1,873)	(1,989)	(3,862)	(9.8)
Total Pharmaceuticals gross to net sales adjustments	**(4,873)**	**(2,866)**	**(7,739)**	**(19.6)**
Pharmaceuticals net sales 2014			**31,790**	**80.4**
2013				
Pharmaceuticals gross sales subject to deductions			**40,188**	**100.0**
US-specific healthcare plans and program rebates	(2,125)		(2,125)	(5.3)
Non-US-specific healthcare plans and program rebates	(1,368)	(802)	(2,170)	(5.4)
Non-healthcare plans and program-related rebates, returns and other deductions	(1,731)	(1,948)	(3,679)	(9.2)
Total Pharmaceuticals gross to net sales adjustments	**(5,224)**	**(2,750)**	**(7,974)**	**(19.8)**
Pharmaceuticals net sales 2013			**32,214**	**80.2**

Impairment of Goodwill, Intangible Assets and Property, Plant and Equipment

We review long-lived intangible assets and property, plant and equipment for impairment whenever events or changes in circumstance indicate that the asset's balance sheet carrying amount may not be recoverable. Goodwill, the Alcon brand-name and other currently not amortized intangible assets are reviewed for impairment at least annually.

An asset is generally considered impaired when its balance sheet carrying amount exceeds its estimated recoverable amount, which is defined as the higher of its fair value less costs of disposal and its value in use. Usually, Novartis adopts the fair value less costs of disposal method for its impairment evaluation. In most cases no directly observable market inputs are available to measure the fair value less

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costs of disposal. Therefore an estimate of fair value less costs of disposal is derived indirectly and is based on net present value techniques utilizing post-tax cash flows and discount rates. In the limited cases where the value in use method is applied, net present value techniques are utilized using pre-tax cash flows and discount rates.

Fair value reflects estimates of assumptions that market participants would be expected to use when pricing the asset and for this purpose management considers the range of economic conditions that are expected to exist over the remaining useful life of the asset. The estimates used in calculating net present values are highly sensitive, and depend on assumptions specific to the nature of the Group's activities with regard to:

- amount and timing of projected future cash flows;
- future tax rates;
- behavior of competitors (launch of competing products, marketing initiatives, etc.); and
- appropriate discount rate.

Due to the above factors and those further described in "Item 18. Financial Statements Note 1", actual cash flows and values could vary significantly from forecasted future cash flows and related values derived using discounting techniques.

The recoverable amount of cash-generating units and related goodwill is usually based on the fair value less costs of disposal derived from applying discounted future cash flows based on the key assumptions in the following table:

	Pharmaceuticals	Alcon	Sandoz
	%	%	%
Cash flows growth rate assumptions after forecast period	1	3	0 to 2
Discount rate (post-tax)	6	6	6

In 2015, intangible asset impairment charges for continuing operations of $206 million were recognized, of which $120 million were recorded in the Alcon Division and $86 million in total in the Pharmaceuticals and Sandoz divisions.

In 2014, intangible asset impairment charges of continuing operations amounted to $347 million ($302 million in the Pharmaceuticals Division and $45 million in total in the Sandoz and Alcon divisions).

In 2015, the reversal of impairment charges recorded in prior years amounted to $40 million (2014: $70 million).

Goodwill and other intangible assets represent a significant part of our consolidated balance sheet, primarily due to acquisitions. Although no significant additional impairments are currently anticipated, impairment evaluation could lead to material impairment charges in the future. For more information, see "Item 18. Financial Statements Note 11".

Additionally, net impairment charges for property, plant and equipment from continuing operations during 2015 amounted to $68 million (2014: $44 million).

Trade Receivables

Trade receivables are initially recognized at their invoiced amounts including any related sales taxes less adjustments for estimated revenue deductions such as rebates, charge backs and cash discounts.

Provisions for doubtful trade receivables are established once there is an indication that it is likely that a loss will be incurred. These provisions represent the difference between the trade receivable's

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carrying amount in the consolidated balance sheet and the estimated net collectible amount. Significant financial difficulties of a customer, such as probability of bankruptcy, financial reorganization, default or delinquency in payments are considered indicators that recovery of the trade receivable is doubtful. Trade receivable balances include sales to drug wholesalers, retailers, private health systems, government agencies, managed care providers, pharmacy benefit managers and government-supported healthcare systems. Novartis continues to monitor sovereign debt issues and economic conditions in Greece, Italy, Portugal, Spain and other countries, and evaluates trade receivables in these countries for potential collection risks. Substantially all of the trade receivables overdue from such countries are due directly from local governments or from government-funded entities. Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time that it takes to collect these trade receivables and may require Novartis to re-evaluate the collectability of these trade receivables in future periods.

Contingent Consideration

In a business combination or divestment of a business, it is necessary to recognize contingent future payments to previous or from new owners representing contractually defined potential amounts as a liability or asset. Usually for Novartis these are linked to milestone or royalty payments related to certain assets and are recognized as a financial liability or asset at their fair value which is then re-measured at each subsequent reporting date. These estimations typically depend on factors such as technical milestones or market performance and are adjusted for the probability of their likelihood of payment and if material, appropriately discounted to reflect the impact of time. Changes in the fair value of contingent liabilities in subsequent periods are recognized in the consolidated income statement in "Cost of goods sold" for currently marketed products and in "Research & Development" for IPR&D. Changes in contingent assets are recognized in "Other income and expense". The effect of unwinding the discount over time is recognized in "Interest expense" in the consolidated income statement. Novartis does not recognize contingent consideration associated with asset purchases outside of a business combination that are conditional upon future events which are within its control until such time as there is an unconditional obligation. If the contingent consideration is outside the control of Novartis, a liability is recognized once it becomes probable that the contingent consideration will become due. In both cases, if appropriate, a corresponding asset is recorded.

Impairment of Associated Companies Accounted for at Equity

Novartis considers investments in associated companies for impairment evaluation whenever there is a quoted share price indicating a fair value less than the per-share balance sheet carrying value for the investment. For unquoted investments in associated companies, recent financial information is taken into account to assess whether an impairment evaluation is necessary.

If the recoverable amount of the investment is estimated to be lower than the balance sheet carrying amount an impairment charge is recognized for the difference in the consolidated income statement under "Income from associated companies".

Retirement and Other Post-Employment Benefit Plans

We sponsor pension and other post-employment benefit plans in various forms that cover a significant portion of our current and former associates. For post-employment plans with defined benefit obligations, we are required to make significant assumptions and estimates about future events in calculating the expense and the present value of the liability related to these plans. These include assumptions about the interest rates we apply to estimate future defined benefit obligations and net periodic pension expense as well as rates of future pension increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates.

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Assumptions and estimates used by the Group may differ materially from the actual results we experience due to changing market and economic conditions, higher or lower withdrawal rates, and longer or shorter life spans of participants among other factors. For example, in 2015, a decrease in the interest rate we apply in determining the present value of the 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 95% of the Group total defined benefit pension obligation, by approximately $0.8 billion. Similarly, if the 2015 interest rate had been one quarter of one percentage point lower than actually assumed, net periodic pension cost for pension plans in these countries, which represent about 88% of the Group's total net periodic pension cost for pension plans, would have increased by approximately $22 million. Depending on events, such differences could have a material effect on our total equity. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 18. Financial Statements Note 25".

Contingencies

A number of Group companies are involved in various government investigations and legal proceedings (intellectual property, sales and marketing practices, product liability, commercial, employment and wrongful discharge, environmental claims, etc.) arising out of the normal conduct of their businesses. For more information, see "Item 18. Financial Statements Note 20".

We record accruals for contingencies when it is probable that a liability has been incurred and the amount can be reliably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For significant product liability cases the accrual is actuarially determined based on factors such as past experience, amount and number of claims reported, and estimates of claims incurred but not yet reported. Expected legal defense costs are accrued when the amount can be reliably estimated.

In some instances, the inherent uncertainty of litigation, the resources required to defend against governmental actions, the potential impact on our reputation, and the potential for exclusion from government reimbursement programs in the US and other countries have contributed to decisions by Novartis and other companies in our industry to enter into settlement agreements with governmental authorities in the absence of an acknowledgement of legal liability. These settlements have had in the past, and may continue in the future, to involve large cash payments, including potential repayment of amounts that were allegedly improperly obtained and other penalties including treble damages. In addition, settlements of governmental healthcare fraud cases often require companies to enter into corporate integrity 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 will expire in 2020. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

Provisions are recorded for environmental remediation costs when expenditure on remedial work is probable and the cost can be reliably estimated. Remediation costs are provided for under "Non-current liabilities" in the Group's consolidated balance sheet.

Provisions relating to estimated future expenditure for liabilities do not usually reflect any insurance or other claims or recoveries, since these are only recognized as assets when the amount is reasonably estimable and collection is virtually certain.

Research & Development

Internal Research & Development costs are fully charged to the consolidated income statement in the period in which they are incurred. We consider that regulatory and other uncertainties inherent in the development of new products preclude the capitalization of internal development expenses as an

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intangible asset usually until marketing approval from the regulatory authority is obtained in a relevant major market, such as for the US, the EU, Switzerland or Japan.

Healthcare Contributions

In many countries our subsidiaries are required to make contributions to the countries' healthcare costs as part of programs other than the ones mentioned above under deductions from revenues. The amounts to be paid depend on various criteria such as the subsidiary's market share or sales volume compared to certain targets. Considerable judgment is required in estimating these contributions as not all data is available when the estimates need to be made.

The largest of these healthcare contributions relates to the US Healthcare Reform fee, which was introduced in 2011. This fee is an annual levy to be paid by US pharmaceutical companies, including various Novartis subsidiaries, based on each company's qualifying sales as a percentage of the prior year's government-funded program sales. This pharmaceutical fee levy is recognized in "Other expense".

On July 25, 2014, the US Department of the Treasury and the US Internal Revenue Service issued final guidance on this pharmaceutical fee levy which stipulated that instead of a liability being estimated and recognized immediately with the first qualifying sale in the following fee year, as had been industry practice, the levy is owed in the year in which the sales occur.

As a result of this final guidance, in 2014, "Other expense" includes the recurring non-tax deductible annual expense of approximately $200 million for the 2014 pharmaceutical fee levy, as well as the non-tax deductible expense of $204 million for the 2013 pharmaceutical fee levy. $204 million of this charge has been considered as an additional exceptional charge in 2014 since it results from the change in timing of recognition of the pharmaceutical fee levy as required by the final guidance.

In addition, effective 2013, the US government also implemented a medical device sales tax which is levied on the Alcon Division's US sales of products which are considered surgical devices under the law. This medical device tax is initially included in the cost of inventory as, for Alcon, the tax is usually levied on intercompany sales. It is expensed as cost of goods sold when the inventory is sold to third parties.

Taxes

We prepare and file our tax returns based on an interpretation of tax laws and regulations, and record estimates based on these judgments and interpretations. Our tax returns are subject to examination by the competent taxing authorities, which may result in an assessment being made requiring payments of additional tax, interest or penalties. Inherent uncertainties exist in our estimates of our tax positions. We believe that our estimated amounts for current and deferred tax assets or liabilities, including any amounts related to any uncertain tax positions, are appropriate based on currently known facts and circumstances.

New Accounting Pronouncements

See "Item 18. Financial Statements Note 1".

Internal Control Over Financial Reporting

The Group's management has assessed the effectiveness of internal control over financial reporting. The Group's independent statutory auditor also issued an opinion on the effectiveness of internal control over financial reporting. Both the Group's management and its external auditors concluded that the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015.

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FACTORS AFFECTING RESULTS OF OPERATIONS

Long-term demographic trends and changing lifestyles are driving increased demand for healthcare around the world, while advances in science and technology are opening new frontiers in patient treatments. In the coming years, these trends are expected to drive steady growth overall in the healthcare market and accelerate growth in key segments of our business. At the same time, the current business and regulatory environment poses significant risks and potential impediments to our growth and to the growth of the healthcare industry.

Transformational Changes Fueling Demand

Aging population and shifting behaviors

Scientific advances and increased access to healthcare are contributing to a rise in life expectancy, increasing the proportion of elderly people worldwide. According to United Nations projections, the number of people over the age of 60 is expected to rise by 500 million, reaching 1.4 billion, by 2030.

The aging of the world's population has contributed to an increase in chronic illnesses that are prevalent among the elderly, such as cancer, heart disease, respiratory ailments, diabetes and eye disease. A global shift toward more sedentary lifestyles is also increasing demand for healthcare. In the last 20 years, obesity rates have doubled among adults and tripled among children.

Novartis has developed new treatments to address some of these growing health threats and we plan to continue research and development activities in these areas.

In 2015, for example, Novartis received approval from the US Food and Drug Administration (FDA) and the European Commission for *Entresto* in chronic heart failure with reduced ejection fraction, which affects more than two million people in the United States and more than five million people in Europe. Regulatory decisions were based on the PARADIGM-HF study, which showed a 20% reduction in cardiovascular deaths versus an ACE inhibitor, the current standard of care in heart failure.

Global rise in healthcare spending

Increased demand for healthcare around the world has translated into rising healthcare costs. If growth in healthcare spending were to continue at the current pace, global outlays could more than double by 2025 to $15 trillion. At the same time, economic uncertainty and tight budgets are prompting many governments, healthcare insurers and consumers to look for ways to moderate spending.

In the context of these trends, we believe that our portfolio spanning pharmaceuticals, generics and eye care, is well-positioned to meet the evolving needs of patients and healthcare systems. For example, the use of generic medicines and biosimilars helps reduce healthcare costs and free up resources for new innovative medicines. Indeed, the global biosimilars market is expected to reach $35 billion by 2020 from an estimated $1.3 billion in 2013, according to a report by Allied Market Research. Our Sandoz Division is a global leader in biosimilars, with three products on the market in Europe and ten major filings (including etanercept and pegfilgrastim, which were submitted in 2015) planned in the next three years. In 2015, Sandoz became the first company to win approval for a biosimilar in the United States under the pathway created by the Biologics Price Competition and Innovation Act.

Scientific advances opening new opportunities

As scientific research has become more sophisticated, we have developed a better understanding of the genetic basis of diseases. This has given rise to a new generation of innovative therapies that could more effectively target the underlying causes of disease.

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For example, our investigational therapy CTL019 works by reprogramming a patient's own T-cells to hunt cancer cells that express specific proteins. After they have been reprogrammed, the T cells are re-introduced into the patient's blood; they proliferate and bind to the targeted cancer cells and destroy them.

Therapies like these have the potential to transform the treatment of disease. We believe that our ability to leverage scientific advances to generate innovative new treatments will enable us to create value over the long-term for society, patients and shareholders.

Convergence of healthcare and technology

From molecular diagnostics to clinical trial recruitment to real world data and analytics, technology continues to play an increasingly important role in the pharmaceutical industry. This is attracting new entrants to the sector. For instance, venture funding grew 200% for digital health companies between 2012 and 2014. Established technology companies such as Google are also using their expertise to expand into healthcare.

While new entrants may shift the competitive landscape, the growing role of technology in healthcare presents an opportunity to pharmaceutical companies like Novartis. Google, for example, is collaborating with our Alcon Division to develop an accommodating contact or intraocular lens for people living with presbyopia. Through the collaboration, we are marrying Google's expertise in miniaturized electronics and microfabrication with Alcon's expertise in the physiology of the eye, as well as clinical development and commercialization of contact and intraocular lenses, to advance a product that has the potential to make reading glasses obsolete.

We also formed a joint investment company with Qualcomm Ventures to support early stage companies with technologies, products or services that "go beyond the pill" to benefit physicians and patients. We recognize the potential of technology to enhance our ability to deliver the right medicine to the right patient at the right time, and seek to partner with experts in emerging technologies to build our expertise in these areas.

Increasingly Challenging Business Environment

Patent expirations and product competition

It is common for pharmaceutical companies to face generic erosion when their products lose patent or other intellectual property protection, and Novartis is no exception. The products of our Pharmaceuticals and Alcon Divisions are generally protected by patent or other intellectual property rights, allowing us to exclusively market those products. The loss of exclusivity has had, and will continue to have, an adverse effect on our results. In 2015, the impact of generic competition on our net sales amounted to $2.2 billion.

Like other players in the pharmaceutical industry, some of our products have begun to face considerable competition due to the expiration of patent or other intellectual property protection. For example:

We already face generic competition in Japan and some EU countries for *Gleevec/Glivec*. In the US, we have resolved patent litigation with certain generic manufacturers. We licensed to a subsidiary of Sun Pharmaceutical Industries the right to market a generic version of *Gleevec* in the US as of February 1, 2016. In the EU, our *Glivec* intellectual property rights are also being challenged by generic manufacturers.

Diovan and *Co-Diovan/Diovan HCT*, which had long been our best-selling product, has generic competitors for *Diovan* in the US, EU and Japan and for *Co-Diovan/Diovan HCT* in the US and EU. In Japan, Novartis resolved patent litigation with a generic manufacturer. Patent protection for *Co-Diovan* will expire in Japan in 2016.

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To counter the impact of patent expirations, we continuously invest in research and development to rejuvenate our portfolio. For example, in 2015, we invested 18% of total net sales in research and development. One measure of the output of our efforts is the performance of our Growth Products products launched in a key market (EU, US, Japan) in 2010 or later, or products with exclusivity in key markets until at least 2019 (except Sandoz, which includes only products launched in the last 24 months). These products accounted for 34% of total net sales in 2015, up 17% from the previous year.

Moreover, while patent expirations present a significant challenge to our Pharmaceuticals and Alcon divisions, they also create an opportunity for Sandoz, our generics business. With our global footprint and advanced technical expertise, we expect Sandoz to help offset the financial impact of generic competition on our branded portfolio.

Heightened regulatory and safety hurdles

Our ability to grow is dependent on our ability to bring new products to market. In recent years, health regulators have raised the bar on product innovation. They are increasingly focused on the benefit-risk profile of pharmaceutical products, emphasizing product safety and improvements over older products in the same therapeutic class. These developments have led to requests for more clinical trial data, the inclusion of significantly higher numbers of patients in those trials, and more detailed analyses of trial outcomes. As a result, the long and expensive process of obtaining regulatory approvals for pharmaceutical products has become even more challenging.

In addition, approved drugs have increasingly been subject to requirements such as risk management plans, comparative effectiveness studies, health technology assessments and post-approval Phase IV clinical trials, making the maintenance of regulatory approvals and achievement of reimbursement for our products increasingly expensive. In addition, these requirements further heighten the risk of recalls, product withdrawals, or loss of market share.

Despite this risk, however, we expect that our focus on accelerating innovation in areas of unmet medical need and demonstrating real improvement in patient outcomes will allow Novartis to continue to bring effective and safe medicines to market.

Increasing pressure on pricing

Against the backdrop of steadily rising healthcare costs, there has been increased scrutiny on drug pricing by governments, media and consumers. Following the launch of Gilead's Sovaldi® in hepatitis C, media focused on the price tag and lawsuits were filed against the company, alleging price-gouging. In 2015, the pricing debate reached a new level of intensity when Turing Pharmaceuticals acquired the rights to the decades-old medicine Daraprim® and raised the price by 5,000%.

We expect scrutiny on prices to continue in 2016 as political pressures mount and 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.

In this environment, we believe that it is more important than ever to demonstrate the value that true innovation brings to the healthcare system. For example, with our psoriasis medicine *Cosentyx*, we demonstrated superiority to Stelara® in a head-to-head study, but still adopted a similar price for our product. Similarly, with *Entresto*, an independent organization called the Institute for Clinical and Economic Review found that its US list price was "well-aligned with the degree of benefit it brings to patients." Furthermore, we expressed a willingness to work with our customers on flexible, performance-based pricing models, where we would only be fully compensated if the drug succeeded in meeting certain targets, such as reducing heart failure hospitalizations and associated costs.

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To manage pricing pressure, we aim to invest in access to real-world data and analytics, explore new technologies and patient management services, and partner with payors to develop and scale outcomes-based commercial models.

Potential liability arising from legal proceedings and government investigations

In recent years, there has been a trend of increasing government investigations and litigation against companies operating in our industry, including in the US and other countries. We are obligated to comply with the laws of all countries in which we operate, with new requirements imposed on us as government and public expectations of corporate behavior develop. We have a significant global compliance program in place, and devote substantial time and resources to ensure that our business is conducted in a legal and publicly acceptable manner. Despite our efforts, any failure to comply with the law could lead to substantial liabilities that may not be covered by insurance and could affect our business and reputation.

Governments and regulatory authorities worldwide are also increasingly challenging practices previously considered to be legal and responding to such challenges and new regulations is costly. 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 costly litigation.

These factors have contributed to recent trends in the pharmaceutical industry to enter into settlement agreements with governmental authorities around the world prior to any formal decision by the authorities. For example, in 2015, our affiliate Novartis Pharmaceuticals Corporation settled litigation in the Southern District of New York related to interactions with specialty pharmacies from 2004 to 2013. The settlement included payments totalling $390 million plus additional legal expenses to plaintiffs, and an agreement to amend and extend for five years an existing corporate integrity agreement (CIA) with the Office of Inspector General of the US Department of Health and Human Services. This resolution and the new CIA obligations provide clear guidelines as we continue to work with independent specialty pharmacies in support of patient care.

Risk of liability and supply disruption from manufacturing issues

The manufacture of our products is both highly regulated and complex, which introduces a greater chance for disruptions and liabilities. Government authorities closely regulate our manufacturing processes, and if those processes fail to meet the necessary requirements, then there is a risk that our production facilities could be shut down. Disturbances in our supply chain can lead to product shortages, significant loss in sales revenue, and litigation. Furthermore, any manufacturing issue compromising supply or quality could have serious consequences for the health of our patients.

Beyond regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For example, biologic products, produced from living plant or animal micro-organisms, comprise a significant portion of the portfolio across the Group. For biologic-based products, even slight deviations at any point in the production process could lead to production failures or recalls. The Group's portfolio also includes a number of sterile products, such as oncology treatments, which are technically complex to manufacture and require strict environmental controls. There is a greater chance of production failures and supply interruptions for these products.

Given the complexity of our manufacturing processes, we have had a multi-year effort in place to ensure adherence to a single high quality standard across the Group. This effort continued to yield steady improvement in 2015: regulatory agencies carried out 192 inspections of Novartis facilities worldwide last year, with 189 or 98.4% resulting in a good or acceptable outcome, in line with prior year. In addition, in September the FDA closed out the May 2013 Warning Letter issued for our Sandoz site in Unterach, Austria.

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Despite this progress, more work remains to be done. In October 2015, the FDA issued a Warning Letter to our Sandoz Division concerning its Indian sites in Kalwe and Turbhe. The letter related to documentation practices in Kalwe and sterile manufacturing practices in Turbhe that were identified during an inspection in August 2014. Novartis took action immediately and has addressed a majority of the issues.

Risk assessment and disclosures

The Risk Committee of the Board ensures the Group has implemented an appropriate and effective risk management system and process. It reviews with management and internal audit the identification, prioritization and management of the risks, the accountabilities and roles of the functions involved with risk management, the risk portfolio and the related actions implemented by management. The Risk Committee informs the Board of Directors on a periodic basis.

The Group Risk Office coordinates and aligns the risk management processes, and reports to the Risk Committee on a regular basis on risk assessment and risk management. Organizational and process measures have been designed to identify and mitigate risks at an early stage. Organizationally, the responsibility for risk assessment and management is allocated to the divisions, with specialized Corporate functions such as Group Finance, Group Quality Assurance, Corporate Health, Safety and Environment, Business Continuity Management, Integrity and Compliance, and the Business Practices Office providing support and controlling the effectiveness of the risk management by the divisions and functions in these respective areas.

Financial risk management is described in more detail, see "Item 18. Financial Statements Note 29".

NON-IFRS MEASURES AS DEFINED BY NOVARTIS

Novartis uses certain non-IFRS metrics when measuring performance, especially when measuring current year results against prior periods, including core results, constant currencies, free cash flow and net debt.

Despite the use of these measures by management in setting goals and measuring the Group's performance, these are non-IFRS measures that have no standardized meaning prescribed by IFRS. As a result, such measures have limits in their usefulness to investors.

Because of their non-standardized definitions, the non-IFRS measures (unlike IFRS measures) may not be comparable to the calculation of similar measures of other companies. These non-IFRS measures are presented solely to permit investors to more fully understand how the Group's management assesses underlying performance. These non-IFRS measures are not, and should not be viewed as, a substitute for IFRS measures.

As an internal measure of Group performance, these non-IFRS measures have limitations, and the Group's performance management process is not solely restricted to these metrics.

Core Results

The Group's core results including core operating income, core net income and core earnings per share exclude the amortization of intangible assets, impairment charges, expenses relating to divestments, the integration of acquisitions and restructuring charges that exceed a threshold of $25 million, as well as other income and expense items that management deems exceptional and that are or are expected to accumulate within the year to be over a $25 million threshold.

Novartis believes that investor understanding of the Group's performance is enhanced by disclosing core measures of performance because, since they exclude items which can vary significantly from year to

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year, the core measures enable better comparison of business performance across years. For this same reason, Novartis uses these core measures in addition to IFRS and other measures as important factors in assessing the Group's performance.

The following are examples of how these core measures are utilized:

- In addition to monthly reports containing financial information prepared under IFRS, senior management receives a monthly analysis incorporating these core measures.

- Annual budgets are prepared for both IFRS and core measures.

A limitation of the core measures is that they provide a view of the Group's operations without including all events during a period, such as the effects of an acquisition or amortization of purchased intangible assets.

Constant Currencies

Changes in the relative values of non-US currencies to the US dollar can affect the Group's financial results and financial position. To provide additional information that may be useful to investors, including changes in sales volume, we present information about our net sales and various values relating to operating and net income that are adjusted for such foreign currency effects.

Constant currency calculations have the goal of eliminating two exchange rate effects so that an estimate can be made of underlying changes in the consolidated income statement excluding the impact of fluctuations in exchange rates:

- the impact of translating the income statements of consolidated entities from their non-$ functional currencies to $; and

- the impact of exchange rate movements on the major transactions of consolidated entities performed in currencies other than their functional currency.

We calculate constant currency measures by translating the current year's foreign currency values for sales and other income statement items into $ using the average exchange rates from the prior year and comparing them to the prior year values in $.

We use these constant currency measures in evaluating the Group's performance, since they may assist us in evaluating our ongoing performance from year to year. However, in performing our evaluation, we also consider equivalent measures of performance which are not affected by changes in the relative value of currencies.

Growth Rate Calculation

For ease of understanding, Novartis uses a sign convention for its growth rates such that a reduction in operating expenses or losses compared to the prior year is shown as a positive growth.

Free Cash Flow

Novartis defines free cash flow as cash flow from operating activities and cash flow associated with the purchase or sale of property, plant and equipment, intangible, other non-current and financial assets. Cash flows in connection with the acquisition or divestment of subsidiaries, associated companies and non-controlling interests in subsidiaries are not taken into account to determine free cash flow.

Free cash flow is presented as additional information because Novartis considers it to be a useful indicator of the Group's ability to operate without reliance on additional borrowing or use of existing cash. Free cash flow is a measure of the net cash generated that is available for debt repayment, investment in strategic opportunities and for returning to shareholders. Novartis uses free cash flow in internal

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comparisons of results from the Group's divisions. Free cash flow is not intended to be a substitute measure for cash flow from operating activities (as determined under IFRS).

Net debt

Novartis defines net debt as current and non-current financial debt less cash and cash equivalents, current investments and derivative financial instruments. Net debt is presented as additional information because management believes it is a useful supplemental indicator of the Group's ability to pay dividends, to meet financial commitments and to invest in new strategic opportunities, including strengthening its balance sheet.

Novartis Cash Value Added

The Novartis Cash Value Added (NCVA) is a metric that is based on what the company assesses to be its cash flow return less a capital charge on gross operating assets. NCVA is used as the primary internal financial measure for determining payouts under the new Long-Term Performance Plan (LTPP) introduced in 2014. More information on NCVA is presented as part of the Compensation report, see "Item 6.B Compensation".

Novartis Economic Value Added

Novartis utilizes its own definition for measuring Novartis Economic Value Added (NVA), which is utilized for determining payouts under the Old Long-Term Performance Plan (OLTPP). The following table shows NVA for 2015 and 2014:

	Year ended Dec 31, 2015	Year ended Dec 31, 2014	Change in $
	$ m	$ m	%
Operating income from continuing operations	**8,977**	**11,089**	**(19)**
Income from associated companies	266	1,918	(86)
Operating interest	(298)	(306)	3
Operating tax	(1,937)	(2,565)	24
Capital charge	(6,164)	(5,938)	(4)
Novartis Economic Value Added from continuing operations	**844**	**4,198**	**(80)**
Novartis Economic Value Added from discontinued operations	10,808	(678)	nm
Total Novartis Economic Value Added	**11,652**	**3,520**	**231**

Operating interest is the internal charge on average working capital based on the short-term borrowing rules of the entity owning them.

Operating tax is the internal tax charge for each entity applying the applicable tax rate to the operational profit before tax unadjusted for tax-disallowed items or tax loss carryforwards.

The capital charge is the notional interest charge on the average non-current assets of operations based on an internally calculated weighted average cost of capital for the Group.

The NVA for continuing operations decreased to $844 million in 2015 from $4.2 billion in the prior-year, mainly on account of the negative currency effect on operating income and lower income from associated companies, which included in the prior year exceptional one-time gains from the sale of the shares of Idenix ($0.8 billion) and LTS ($0.4 billion).

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The NVA for discontinued operations in 2015 was mainly driven by the $12.7 billion exceptional pre-tax gains form the portfolio transformation transactions with GSK and Lilly.

Additional Information

EBITDA

Novartis defines earnings before interest, tax, depreciation and amortization (EBITDA) as operating income from continuing operations excluding depreciation of property, plant and equipment (including any related impairment charges) and amortization of intangible assets (including any related impairment charges).

	2015	2014	Change
	$ m	$ m	$ m
Operating income from continuing operations	**8,977**	**11,089**	**(2,112)**
Depreciation of property, plant & equipment	1,470	1,586	(116)
Amortization of intangible assets	3,755	2,775	980
Impairments of property, plant & equipment and intangible assets	246	321	(75)
EBITDA from continuing operations	**14,448**	**15,771**	**(1,323)**

Enterprise Value

Enterprise value represents the total amount that shareholders and debt holders have invested in Novartis, less the Group's liquidity.

	Dec 31, 2015	Dec 31, 2014	Change
	$ m	$ m	$ m
Market capitalization	208,321	223,728	(15,407)
Non-controlling interests	76	78	(2)
Financial debts and derivatives	21,931	20,411	1,520
Liquidity	(5,447)	(13,862)	8,415
Enterprise value	**224,881**	**230,355**	**(5,474)**
Enterprise value/EBITDA	**16**	**15**	

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2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS GROUP

2015	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, including restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit from continuing operations	**32,983**	**3,666**	**126**		**125**	**36,900**
Operating income from continuing operations	**8,977**	**3,709**	**369**	**182**	**553**	**13,790**
Income before taxes from continuing operations	**8,134**	**4,132**	**369**	**182**	**1,275**	**14,092**
Taxes from continuing operations[5]	(1,106)					(2,051)
Net income from continuing operations	**7,028**					**12,041**
Net income/loss from discontinued operations[6]	10,766					(256)
Net income	**17,794**					**11,785**
Basic EPS from continuing operations ($)[7]	**2.92**					**5.01**
Basic EPS from discontinued operations ($)[7]	4.48					(0.11)
Total basic EPS ($)[7]	**7.40**					**4.90**
The following are adjustments to arrive at Core Gross Profit from continuing operations						
Other revenues	947				(28)	919
Cost of goods sold	(17,404)	3,666	126		153	(13,459)
The following are adjustments to arrive at Core Operating Income from continuing operations						
Marketing & Sales	(11,772)				43	(11,729)
Research & Development	(8,935)	43	40		114	(8,738)
General & Administration	(2,475)				86	(2,389)
Other income	2,049		(56)	(283)	(887)	823
Other expense	(2,873)		259	465	1,072	(1,077)
The following are adjustments to arrive at Core Income before taxes from continuing operations						
Income from associated companies	266	423			292	981
Other financial income and expense	(454)				430	(24)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; Income from associated companies includes $423 million for the Novartis share of the estimated Roche core items.

(2)

Impairments: Cost of goods sold, Research & Development and Other expense consist principally of net impairment charges or reversals related to intangible assets, property, plant and equipment, and financial assets; Other income includes a reversal of an impairment related to property, plant and equipment.

(3)

Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include items related to the portfolio transformation.

(4)

Other exceptional items: Other revenues and Other income include additional gains from product divestments; Cost of goods sold and Other expense include charges for the Group-wide rationalization of manufacturing sites; Cost of goods sold also includes an inventory write-off; Marketing & Sales, Research & Development and Other expense include other restructuring charges; Research & Development also includes expenses related to product acquisitions; General & Administration includes charges for transforming IT and finance processes and expenses related to setup costs for Novartis Business Services; Other income also includes a gain of $110 million from a Swiss pension plan amendment and items related to portfolio transformation; Other expense also includes legal settlement provisions; Income from associated companies includes $292 million for the Novartis share of the estimated OTC joint venture core items; Other financial income and expense includes a charge of $410 million related to Venezuela consisting of foreign exchange losses ($211 million), the loss on the sale of PDVSA bonds ($127 million) and the monetary loss due to hyperinflation ($72 million).

(5)

Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax

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impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not always the case for items arising from legal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments for continuing operations of $6.0 billion to arrive at the core results before tax amounts to $945 million. The average tax rate on the adjustments for continuing operations is 15.9%.

(6) For details on discontinued operations reconciliation from IFRS to core net income, see " Non-IFRS Measures as Defined by Novartis".

(7) Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

2014	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, including restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit from continuing operations	**36,289**	**2,692**	**(21)**		**(139)**	**38,821**
Operating income from continuing operations	**11,089**	**2,743**	**433**	**33**	**175**	**14,473**
Income before taxes from continuing operations	**12,272**	**3,000**	**434**	**33**	**(1,058)**	**14,681**
Taxes from continuing operations[5]	(1,545)					(2,028)
Net income from continuing operations	**10,727**					**12,653**
Net income/loss from discontinued operations[6]	(447)					102
Net income	**10,280**					**12,755**
Basic EPS from continuing operations ($)[7]	**4.39**					**5.19**
Basic EPS from discontinued operations ($)[7]	(0.18)					0.04
Total basic EPS ($)[7]	**4.21**					**5.23**
The following are adjustments to arrive at Core Gross Profit from continuing operations						
Other revenues	1,215				(302)	913
Cost of goods sold	(17,345)	2,692	(21)		163	(14,511)
The following are adjustments to arrive at Core Operating Income from continuing operations						
Marketing & Sales	(12,377)				22	(12,355)
Research & Development	(9,086)	48	298		17	(8,723)
General & Administration	(2,616)				64	(2,552)
Other income	1,391		(15)		(813)	563
Other expense	(2,512)	3	171	33	1,024	(1,281)
The following are adjustments to arrive at Core Income before taxes from continuing operations						
Income from associated companies	1,918	257	1		(1,233)	943

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; Other expense includes amortization of intangible assets; Income from associated companies includes $257 million for the Novartis share of the estimated Roche core items.

(2) Impairments: Cost of goods sold, Research & Development, Other income and Other expense consist principally of net impairment charges or reversals related to intangible assets, property, plant and equipment and financial assets.

(3) Acquisition or divestment related items, restructuring and integration charges: Other expense includes costs related to the portfolio transformation.

(4) Other exceptional items: Other revenues includes an amount for a commercial settlement; Cost of goods sold includes charges for the Group-wide rationalization of manufacturing sites; Marketing & Sales, Research & Development and General & Administration include charges for transforming IT and finance processes; Other income includes product related divestment gains and gains in the Novartis Venture Fund, an insurance recovery net of a deferred amount, a partial reversal of a legal expense provision, a reduction in restructuring provisions, and the impact from a post-retirement medical plan amendment;

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Other expense includes restructuring provision charges, charges for transforming IT and finance processes, an expense related to *Lucentis* in Italy, the expense of $204 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations. Income from associated companies includes gains from the divestment of Idenix and LTS Lohmann Therapie-Systeme AG shareholdings.

(5) Taxes on the adjustments between IFRS and core results of continuing operations take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not always the case for items arising from legal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of $2.4 billion to arrive at the core results before tax amounts to $483 million. This results in the average tax rate on the adjustments being 20.0%.

(6) For details on discontinued operations reconciliation from IFRS to core net income, see " Non-IFRS Measures as Defined by Novartis".

(7) Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

2013	**IFRS results**	**Amortization of intangible assets[1]**	**Impairments[2]**	**Acquisition or divestment related items, including restructuring and integration charges[3]**	**Other exceptional items[4]**	**Core results**
	$ m	**$ m**	**$ m**	**$ m**	**$ m**	**$ m**
Gross profit from continuing operations	**36,137**	**2,615**	**20**		**20**	**38,792**
Operating income from continuing operations	**10,983**	**2,680**	**210**	**331**	**3**	**14,207**
Income before taxes from continuing operations	**10,807**	**2,939**	**210**	**349**	**47**	**14,352**
Taxes from continuing operations[5]	(1,498)					(2,057)
Net income from continuing operations	**9,309**					**12,295**
Net income/loss from discontinued operations[6]	(17)					238
Net income	**9,292**					**12,533**
EPS from continuing operations ($)[7]	**3.76**					**4.99**
EPS from discontinued operations ($)[7]						0.10
EPS ($)[7]	**3.76**					**5.09**
The following are adjustments to arrive at Core Gross Profit from continuing operations						
Cost of goods sold	(16,579)	2,615	20		20	(13,924)
The following are adjustments to arrive at Core Operating Income from continuing operations						
Marketing & Sales	(12,638)				27	(12,611)
Research & Development	(9,071)	61	86		39	(8,885)
General & Administration	(2,603)				25	(2,578)

Other income	1,205		(52)		(505)	648
Other expense	(2,047)	4	156	331	397	(1,159)
The following are adjustments to arrive at Core Income before taxes from continuing operations						
Income from associated companies	599	259		18		876
Other financial income and expense	(92)				44	(48)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms; Other expense includes amortization of intangible assets; Income from associated companies includes $259 million for the Novartis share of the estimated Roche core items.

(2) Impairments: Cost of goods sold, Research & Development, Other income and Other expense include principally net impairment charges or reversals related to intangible assets and property, plant and equipment, mainly related to the Group-wide rationalization of manufacturing sites.

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(3) Acquisition or divestment related items, restructuring and integration charges: Other expense includes Alcon integration costs. Income from associated companies includes restructuring charges related to Roche.

(4) Other exceptional items: Cost of goods sold, Other income and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Marketing & Sales includes charges related to termination of a co-promotional contract; Research & Development also includes a net increase of contingent consideration liabilities related to acquisitions; General & Administration includes exceptional IT-related costs; Other income includes divestment gains, a reversal of a Corporate provision, income from post-retirement medical plan amendments and reduction in restructuring charge provisions; Other expense includes a restructuring provision charge, provisions for legal matters, and charges for transforming IT and finance processes; Other financial income and expense includes devaluation losses of $44 million related to Venezuela.

(5) Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on exceptional items although this is not always the case for items arising from legal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of $3.5 billion to arrive at the core results before tax amounts to $559 million. This results in the average tax rate on the adjustments is 15.8%.

(6) For details on discontinued operations reconciliation from IFRS to core net income, see " Non-IFRS Measures as Defined by Novartis".

(7) Earnings per share (EPS) is calculated on the amount of net income attributable to shareholders of Novartis AG.

2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS PHARMACEUTICALS

2015	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, including restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**23,993**	**1,262**	**(20)**		**88**	**25,323**
Operating income	**7,597**	**1,290**	**12**	**192**	**329**	**9,420**
The following are adjustments to arrive at Core Gross Profit						
Other revenues	790				(28)	762
Cost of goods sold	(7,379)	1,262	(20)		116	(6,021)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(7,789)				43	(7,746)
Research & Development	(7,232)	28	39		112	(7,053)
Other income	1,145		(56)	(22)	(743)	324
Other expense	(1,583)		49	214	829	(491)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Cost of goods sold and Other income include a reversal of intangible asset impairments; Research & Development includes impairment charges for in process projects and termination of collaboration and license agreements; Other expense includes impairment charges related to property, plant and equipment and financial assets.

(3) Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include income and costs related to the portfolio transformation.

(4) Other exceptional items: Other revenues and Other income include additional gains from product divestments; Cost of goods sold and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold also includes an inventory write-off; Marketing & Sales, Research & Development and Other expense include other restructuring charges; Research & Development also includes expenses related to product acquisitions; Other income also includes a gain from a Swiss pension plan amendment; Other expense also includes legal settlement provisions.

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2014	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, including restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**25,793**	**238**	**(58)**		**127**	**26,100**
Operating income	**8,471**	**276**	**266**	**33**	**468**	**9,514**
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(6,889)	238	(58)		127	(6,582)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(8,178)				2	(8,176)
Research & Development	(7,331)	38	289		7	(6,997)
General & Administration	(1,009)				1	(1,008)
Other income	734		(13)		(451)	270
Other expense	(1,538)		48	33	782	(675)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Cost of good sold includes partial reversal of previously impaired production assets, partly offset by the impairment of intangible assets related to a marketed product; Research & Development includes impairment charges for in process projects and termination of collaboration and license agreements; Other income relates to impairment reversals of property, plant and equipment; Other expense includes impairment charges related to property, plant and equipment and financial assets.

(3) Acquisition or divestment related items, including restructuring and integration charges: Other expense includes costs related to the acquisition of GSK oncology assets.

(4) Other exceptional items: Cost of goods sold, Research & Development and Marketing & Sales include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Other income includes an insurance recovery from Corporate related to exchange risks, gains related to the rationalization of manufacturing sites, the impact from a post-retirement medical plan amendment, as well as additional gains from divestments announced in prior periods; Other expense include restructuring charges, an expense related to *Lucentis* in Italy and an expense of $157 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations.

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2013	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m	$ m	$ m
Gross profit	**26,258**	**228**		**6**	**26,492**
Operating income	**9,376**	**278**	**74**	**(205)**	**9,523**
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(6,655)	228		6	(6,421)
The following are adjustments to arrive at Core Operating Income					
Marketing & Sales	(8,514)			27	(8,487)
Research & Development	(7,242)	50	29	2	(7,161)
Other income	699		(46)	(390)	263
Other expense	(774)		91	150	(533)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Research & Development includes impairment charges for in process projects; Other income includes charges related to the reversal of impairment charges related to aliskiren production equipment for which an alternative use has been found; Other expense includes impairment charges related to property, plant and equipment.

(3) Other exceptional items: Cost of goods sold includes principally restructuring charges related to the Group-wide rationalization of manufacturing sites offset by a provision reduction related to aliskiren; Marketing & Sales includes charges related to termination of a co-promotional contract; Research & Development includes restructuring charges; Other income includes principally divestment gains and a reduction in restructuring charge provisions; Other expense includes restructuring charges and provisions for legal matters.

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2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS ALCON

2015	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m	$ m	$ m
Gross profit	**4,729**	**2,049**	**119**	**4**	**6,901**
Operating income	**794**	**2,063**	**121**	**85**	**3,063**
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,153)	2,049	119	4	(2,981)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(926)	14	1	2	(909)
General & Administration	(544)			32	(512)
Other income	58			(13)	45
Other expense	(125)		1	60	(64)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Cost of goods sold includes impairment charges related to intangible assets; Research & Development and Other expense include impairment charges related to property, plant and equipment.

(3) Other exceptional items: Cost of goods sold includes net restructuring charges related to the Group-wide rationalization of manufacturing sites; Research & Development includes non capitalized costs for the US; General & Administration includes charges for transforming IT and finance processes; Other income includes a gain from a Swiss pension plan amendment and a partial reversal of restructuring charges; Other expense includes other restructuring charges and a legal settlement.

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2014	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m	$ m	$ m
Gross profit	**5,717**	**2,056**		**26**	**7,799**
Operating income	**1,597**	**2,064**	**6**	**144**	**3,811**
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,193)	2,056		26	(3,111)
The following are adjustments to arrive at Core Operating Income					
Marketing & Sales	(2,474)			20	(2,454)
Research & Development	(928)	8	7	10	(903)
General & Administration	(613)			45	(568)
Other income	79		(1)	(52)	26
Other expense	(184)			95	(89)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Research & Development includes impairment charges for in process projects; Other income includes a reversal of impairment charges related to property, plant and equipment.

(3) Other exceptional items: Cost of goods sold and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Marketing & Sales and General & Administration include charges for transforming IT and finance processes; Research & Development includes a net increase of contingent consideration liabilities related to acquisitions; Other income includes the reversal of restructuring charges related to the Group-wide rationalization of manufacturing sites, as well as the impact from a post-retirement medical plan amendment; Other expense also includes an expense of $29 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations.

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2013	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**5,673**	**1,980**			**12**	**7,665**
Operating income	**1,232**	**1,989**	**61**	**330**	**82**	**3,694**
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(4,900)	1,980			12	(2,908)
The following are adjustments to arrive at Core Operating Income						
Research & Development	(1,042)	9	57		37	(939)
General & Administration	(589)				25	(564)
Other income	79				(40)	39
Other expense	(437)		4	330	48	(55)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Research & Development includes impairment charges related to in process projects; Other expense includes impairment charges related to property, plant and equipment.

(3) Acquisition or divestment related items, restructuring and integration charges: Other expense reflects acquisition-related Alcon integration and restructuring charges.

(4) Other exceptional items: Cost of goods sold includes net restructuring charges related to the Group-wide rationalization of manufacturing sites offset by the release of a contingent consideration liability related to recent acquisitions; Research & Development includes a net increase of contingent consideration liabilities related to acquisitions; General & Administration includes exceptional IT costs; Other income includes the impact of an income from a post-retirement medical plan amendment; Other expense includes net restructuring charges related to European commercial operations and the Group-wide rationalization of manufacturing sites.

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2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS SANDOZ

2015	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, including restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**3,985**	**355**	**27**		**33**	**4,400**
Operating income	**1,005**	**356**	**124**		**174**	**1,659**
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(5,325)	355	27		33	(4,910)
The following are adjustments to arrive at Core Operating Income						
Research & Development	(777)	1				(776)
Other income	109			(1)	(4)	104
Other expense	(381)		97	1	145	(138)

(1) Amortization of intangible assets: Cost of goods sold include recurring amortization of acquired rights to in-market products and other production-related intangible assets.

(2) Impairments: Cost of goods sold includes impairments of intangible assets; Other expense includes impairment charges related to property, plant and equipment.

(3) Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include items related to the portfolio transformation.

(4) Other exceptional items: Cost of goods sold includes marketable intangible assets not capitalized; Cost of goods sold and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Other income includes a gain from a Swiss pension plan amendment; Other expense also includes a legal settlement.

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2014	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m	$ m	$ m
Gross profit	**4,109**	**398**	**37**	**10**	**4,554**
Operating income	**1,088**	**400**	**47**	**36**	**1,571**
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,751)	398	37	10	(5,306)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(827)	2	2		(823)
Other income	97		(1)	(3)	93
Other expense	(190)		9	29	(152)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Cost of goods sold and Research & Development include charges related to impairment of intangible assets; Other income includes a reversal of impairment charges related to property, plant and equipment; Other expense includes impairment charges related to property, plant and equipment and financial assets.

(3) Other exceptional items: Cost of goods sold and Other expense include net restructuring charges; Other income includes the reversal of restructuring charges; Other expense also includes an expense of $18 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations.

2013	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m		$ m$ m
Gross profit	**3,995**	**407**	**20**	**2**	**4,424**
Operating income	**1,028**	**409**	**17**	**87**	**1,541**
The following are adjustments to arrive at Core Gross Profit					
Cost of goods sold	(5,476)	407	20	2	(5,047)
The following are adjustments to arrive at Core Operating Income					
Research & Development	(787)	2			(785)
Other income	106		(6)		100
Other expense	(240)		3	85	(152)

(1) Amortization of intangible assets: Cost of goods sold includes recurring amortization of acquired rights to in-market products and other production-related intangible assets; Research & Development includes the recurring amortization of acquired rights for technology platforms.

(2) Impairments: Cost of goods sold includes impairment charges related to intangible assets; Other income includes a reversal of impairment charges related to property, plant and equipment; Other expense includes impairment charges related to property, plant and equipment.

(3) Other exceptional items: Cost of goods sold includes net restructuring charges related to the Group-wide rationalization of manufacturing sites; Other expense includes provisions for legal matters.

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2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS CORPORATE

2015	IFRS results	Impairments[1]	Acquisition or divestment related items, including restructuring and integration charges[2]	Other exceptional items[3]	Core results
	$ m		$ m	$ m	$ m$ m
Gross profit	**276**				**276**
Operating loss	**(419)**	**112**	**(10)**	**(35)**	**(352)**
The following are adjustments to arrive at Core Operating Loss					
General & Administration	(648)			54	(594)
Other income	737		(260)	(127)	350
Other expense	(784)	112	250	38	(384)

(1) Impairments: Other expense includes impairment charges related to property, plant and equipment and financial assets.

(2) Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include items related to the portfolio transformation.

(3) Other exceptional items: General & Administration and Other expense include expenses related to setup costs for Novartis Business Services; Other income includes a gain from a Swiss pension plan amendment, a reversal of a provision and items related to portfolio transformation; Other expense also includes a credit for a legal settlement charged to the divisions.

2014	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m		$ m$ m
Gross profit	**670**			**(302)**	**368**
Operating loss	**(67)**	**3**	**114**	**(473)**	**(423)**
The following are adjustments to arrive at Core Gross Profit					
Other revenues	540			(302)	238
The following are adjustments to arrive at Core Operating Loss					
General & Administration	(618)			18	(600)
Other income	481			(307)	174
Other expense	(600)	3	114	118	(365)

(1) Amortization of intangible assets: Other expense includes amortization of intangible assets.

(2)

Impairments: Other expense includes impairment charges related to property, plant and equipment and financial assets.

(3)

Other exceptional items: Other revenues includes an amount for a commercial settlement; General & Administration includes expenses related to setup costs for Novartis Business Services; Other income includes an insurance recovery transferred to Pharmaceuticals net of a deferred amount and gains in the Novartis Venture Fund; Other expense includes charges for transforming IT and finance processes, as well as a provision for a legal settlement.

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2013	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment related items, restructuring and integration charges[3]	Other exceptional items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**211**					**211**
Operating loss	**(653)**	**4**	**58**	**1**	**39**	**(551)**
The following are adjustments to arrive at Core Operating Loss						
Other income	321				(75)	246
Other expense	(596)	4	58	1	114	(419)

(1) Amortization of intangible assets: Other expense includes amortization of intangible assets

(2) Impairments: Other expense includes impairment charges related to property, plant and equipment and to a financial asset.

(3) Acquisition or divestment related items, restructuring and integration charges: Other expense reflects Alcon integration costs.

(4) Other exceptional items: Other income includes a reversal of a provision; Other expense includes charges for transforming IT and finance processes.

2015, 2014 AND 2013 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS DISCONTINUED OPERATIONS

2015	IFRS results	Impairments[1]	Acquisition or divestment related items, including restructuring and integration charges[2]	Other exceptional items[3]	Core results
	$ m	$ m	$ m	$ m	$ m
Gross profit	**267**			**6**	**273**
Operating income/loss	**12,477**	**(83)**	**(12,627)**	**8**	**(225)**
Income/loss before taxes	**12,479**	**(83)**	**(12,627)**	**8**	**(223)**
Taxes[4]	(1,713)				(33)
Net income/loss	**10,766**				**(256)**
EPS ($)[5]	**4.48**				**(0.11)**