NOVARTIS AG
Form 20-F
January 24, 2018

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As filed with the Securities and Exchange Commission on January 24, 2018

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, 2017

OR

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

OR

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

Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

Lichtstrasse 35
4056 Basel, Switzerland

(Address of principal executive offices)

Felix R. Ehrat
Group General Counsel

Novartis AG
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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:

2,317,456,499 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

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ý No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý Accelerated filer o Non-accelerated filer o Emerging growth company o

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

U.S. GAAP o International Financial Reporting Standards as issued by the International Accounting Standards Board ý Other o
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 responsive to 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).

Pursuant to Rule 12b-23 of the Securities Exchange Act of 1934, as amended, we incorporate information for certain items of this Form 20-F by reference to the "Excerpts from Novartis Annual Report 2017" included as Exhibit 99.1 to Form 6-K furnished to the SEC on January 24, 2018 (the Annual Report Excerpts). Therefore the information in this Form 20-F should be read in conjunction with the Annual Report Excerpts. References to content not contained within the Annual Report Excerpts shall not be deemed to be incorporated by reference.

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 similar supervisory body or other top local management body, if applicable. 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," "USD" 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 and are the property of their respective owners.

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; or regarding the potential outcome, or financial or other impact on Novartis, of the strategic review being undertaken to maximize shareholder value of the Alcon Division; or regarding the potential financial or other impact on Novartis or any of our divisions of

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the significant acquisitions and reorganizations of recent years; or regarding the potential impact of the share buyback plan; or regarding potential future sales or earnings of the Novartis Group or any of its divisions or potential shareholder returns; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements.

Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, 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. Neither can there be any guarantee that the strategic review being undertaken to maximize shareholder value of the Alcon Division will reach any particular results, or at any particular time, or that the result of the strategic review will in fact maximize shareholder value. 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 significant acquisitions and reorganizations of recent years. Neither can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Nor 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 or financial results.

In particular, our expectations could be affected by, among other things:

- global trends toward health care cost containment, including ongoing government, payor and general public pricing and reimbursement pressures, such as from increased publicity on pharmaceuticals pricing, and requirements for increased pricing transparency;
- regulatory actions or delays or government regulation generally;
- the potential that the strategic benefits, synergies or opportunities expected from the significant acquisitions and reorganizations of recent years may not be realized or may take longer to realize than expected;
- the inherent uncertainties involved in predicting shareholder returns;
- the uncertainties inherent in the research and development of new healthcare products, including 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;
- safety, quality or manufacturing issues;
- uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally;
- uncertainties involved in the development or adoption of potentially transformational technologies and business models;
- general political and economic conditions, including uncertainties regarding the effects of ongoing instability in various parts of the world;

uncertainties regarding future global exchange rates;

uncertainties regarding future demand for our products; and

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uncertainties regarding potential significant breaches of data security or data privacy, 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, 2017, 2016 and 2015, are included under "Novartis Group consolidated financial statements" on pages 186 to 254 of the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018, and in "Item 18. Financial Statements" in this Form 20-F.

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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,				
	2017	**2016**	**2015**	**2014**	**2013**
	($ millions, except per share information)				
INCOME STATEMENT DATA					
Net sales to third parties from continuing operations	**49,109**	**48,518**	**49,414**	**52,180**	**51,869**
Operating income from continuing operations	**8,629**	**8,268**	**8,977**	**11,089**	**10,983**
Income from associated companies	1,108	703	266	1,918	599
Interest expense	(777)	(707)	(655)	(704)	(683)
Other financial income and expense	39	(447)	(454)	(31)	(92)
Income before taxes from continuing operations	**8,999**	**7,817**	**8,134**	**12,272**	**10,807**
Taxes	(1,296)	(1,119)	(1,106)	(1,545)	(1,498)
Net income from continuing operations	**7,703**	**6,698**	**7,028**	**10,727**	**9,309**
Net income/(loss) from discontinued operations			10,766	(447)	(17)
Group net income	**7,703**	**6,698**	**17,794**	**10,280**	**9,292**
Attributable to:					
Shareholders of Novartis AG	7,703	6,712	17,783	10,210	9,175
Non-controlling interests	0	(14)	11	70	117
Basic earnings per share ($)					
Continuing operations	3.28	2.82	2.92	4.39	3.76
Discontinued operations			4.48	(0.18)	0.00
Total	3.28	2.82	7.40	4.21	3.76
Diluted earnings per share ($)					
Continuing operations	3.25	2.80	2.88	4.31	3.70
Discontinued operations			4.41	(0.18)	0.00
Total	3.25	2.80	7.29	4.13	3.70
Cash dividends[1]	6,495	6,475	6,643	6,810	6,100
Cash dividends per share in CHF[2]	2.80	2.75	2.70	2.60	2.45

(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 2013 through 2016 were approved at the respective AGMs and dividends for 2017 will be proposed to the Annual General Meeting on March 2, 2018 for approval.

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	Year Ended December 31,				
	2017	2016	2015	2014	2013
			($ millions)		
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial instruments	9,485	7,777	5,447	13,862	9,222
Inventories	6,867	6,255	6,226	6,093	7,267
Other current assets	11,856	10,899	11,172	10,805	13,294
Non-current assets	104,871	105,193	108,711	87,826	95,712
Assets related to discontinued operations				6,801	759
Total assets	**133,079**	**130,124**	**131,556**	**125,387**	**126,254**
Trade accounts payable	5,169	4,873	5,668	5,419	6,148
Other current liabilities	18,234	17,336	18,040	19,136	20,170
Non-current liabilities	35,449	33,024	30,726	27,570	25,414
Liabilities related to discontinued operations				2,418	50
Total liabilities	**58,852**	**55,233**	**54,434**	**54,543**	**51,782**
Issued share capital and reserves attributable to shareholders of Novartis AG	74,168	74,832	77,046	70,766	74,343
Non-controlling interests	59	59	76	78	129
Total equity	**74,227**	**74,891**	**77,122**	**70,844**	**74,472**
Total liabilities and equity	**133,079**	**130,124**	**131,556**	**125,387**	**126,254**
Net assets	74,227	74,891	77,122	70,844	74,472
Outstanding share capital	869	896	890	898	912
Total outstanding shares (millions)	2,317	2,374	2,374	2,399	2,426

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 ($)
2013	March 2014	2.45	2.76
2014	March 2015	2.60	2.67
2015	March 2016	2.70	2.70
2016	March 2017	2.75	2.72
2017[1]	March 2018	2.80	2.87[2]

(1) Dividend to be proposed at the Annual General Meeting on March 2, 2018, and to be distributed March 8, 2018.

(2) Translated into US dollars at the December 31, 2017 rate of $1.024 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 18, 2018, as found on Bloomberg Market System, was CHF 1.00 = $1.04.

Year ended December 31, **($ per CHF)**	**Period End**	**Average[1]**	**Low[2]**	**High[2]**
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
2016	0.98	1.01	0.98	1.04
2017	1.02	1.02	0.99	1.04
Month				
August 2017			1.03	1.05
September 2017			1.03	1.06
October 2017			1.00	1.03
November 2017			1.00	1.02
December 2017			1.00	1.02
January 2018 (through January 18, 2018)			1.02	1.04

(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 losses of intellectual property protection.

Major products of our Innovative Medicines Division, as well as certain products of our Sandoz and Alcon Divisions, are protected by patent and other intellectual property rights, which provide us with exclusive rights to market the products, and give us an opportunity to recoup our investments in research and development. However, the strength and duration of those intellectual property rights can vary significantly from product to product and country to country, and they may be successfully challenged by

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third parties or regulatory authorities. 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.

The introduction of generic competition for a patented branded medicine typically results in a significant and rapid reduction in net sales and operating income for the branded 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 a Declaration of Public Interest or 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 intellectual property rights, including conducting so-called "launches at risk" of products that are still under legal challenge for 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 or our other protective measures should fail, then 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.

Our formerly best-selling product *Gleevec/Glivec* faces continued and increasing generic competition in the US, EU and Japan.

Patent protection for the marketed forms of our *Sandostatin* products has expired. Generic versions of *Sandostatin* SC are available in the US, EU and Japan. While there is currently no generic competition in the US, EU or Japan for *Sandostatin LAR*, the long-acting version of *Sandostatin* which represents the majority of our *Sandostatin* sales, such generic competition may arise in the future.

Diovan and *Co-Diovan/Diovan HCT*, which had long been our best-selling product, has generic competitors in the US, EU and Japan. In addition, the single pill combination products *Exforge* and *Exforge HCT*, which contain valsartan, the active ingredient in *Diovan*, face generic competition despite the existence of separate intellectual property covering those products. *Exforge* has generic competition in the US, EU and Japan. *Exforge HCT*, which is not marketed in Japan, has generic competition in the US and may face additional generic competition in the future.

Intellectual property protecting a number of additional major products is either being challenged or will expire at various times in the coming years, raising the possibility of generic competition. Among these products that may begin to face generic competition in one or more major markets during the next three years are *Gilenya*, our everolimus products (*Afinitor/Votubia* and *Certican/Zortress*), *Exjade/Jadenu* and *Lucentis*.

For more information on the patent status of our Innovative Medicines Division's products see "Item 4. Information on the Company Item 4.B Business Overview Innovative Medicines Intellectual Property."

In 2018, we expect an impact on our net sales of about $1.5 billion as a result of the loss of intellectual property protection for our products. 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 2018 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 the

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generic competitor is launched; 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.

Our financial performance depends on the commercial success of key products.

Our financial performance, including our ability to replace revenue and income lost to generic and other competition and to grow our business, depends heavily on the commercial success of our products. If any of our major products were to become subject to problems such as changes in prescription growth rates, unexpected side effects, loss of intellectual property protection, supply chain issues or other product shortages, regulatory proceedings, changes in labeling, publicity affecting doctor or patient confidence in the product, material product liability litigation, or pressure from new or existing competitive products, the adverse impact on our revenue and profit could be significant. In addition, our revenue and profit could be significantly impacted by the timing and rate of commercial acceptance of key new products. See also " Our business is affected by pressures on pricing and reimbursement for our products," below, with regard to the impact of pricing and reimbursement issues on the commercial success of our products.

All of our businesses are broadly faced with intense competition from new products and technological advances from competitors, and 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 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, including *Cosentyx, Lucentis, Gilenya, Sandostatin, Tasigna* and *Afinitor,* are on the market, and others are in development. In addition, numerous companies are seeking to enter the healthcare field to take advantage of their expertise in digital and other new technologies. See " We may fail to develop or take advantage of transformational technologies and business models," below. We may also face new competitors from different regions of the world, including China, which is moving aggressively to expand its role in the sciences and in many industries. Such new competitors may successfully develop products or technologies which could make products of ours uncompetitive or obsolete.

Such competitive products could significantly affect the revenue from our products and our results of operations. This impact could also be compounded to the extent such competition results in us making significant additional investments in marketing and sales, or in research and development.

In particular, our Alcon Division and our US Sandoz business each has suffered declines in sales and profits in recent years due at least in part to increased competition for its products, although Alcon's results improved in 2017, returning to growth. There can be no certainty either that Sandoz US sales will recover, or that Alcon's improved results will be repeated in the coming years. In any event, such competition and the costs of our efforts to improve these businesses' performance, as well as other factors, can be expected to affect the business, financial condition or results of operations of these organizations, at least in the near term. In addition, despite the devotion of significant resources to our efforts to improve the performance of Alcon and Sandoz US, those efforts may ultimately prove insufficient. Should our efforts fail to accomplish their goals, or fail to do so in a timely manner, it could have a material

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adverse impact on our business, financial condition or results of operations beyond the near term, as well. See also " 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 revenue and income and take advantage of new technologies," and " Intense competition from patented and generic pharmaceuticals companies, as well as failure to obtain marketing exclusivity periods for new generic products, or to successfully develop biosimilars and other differentiated products, may have a material adverse effect on the success of our Sandoz Division," 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 revenue 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 new products that address unmet medical needs, are accepted by patients and physicians, are reimbursed by payors, and are commercially successful. To accomplish this, we commit substantial effort, funds and other resources to research and development, both through our own dedicated resources and through collaborations with third parties. However, developing new healthcare products and bringing them to market 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 successful new products that will enable us to replace revenue and income lost to generic and other competition and to grow our business. See also " We may not successfully achieve our goals in transactions or reorganizations," below, with regard to our recent reorganization of our pharmaceutical product development organization.

Using the products of our Innovative Medicines 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 may 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 or to differentiate our product candidate from competitors, 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 the "Brexit" vote in the UK, the EU has decided to move the headquarters of the EU's health authority, the EMA, from the UK to the Netherlands by March 2019. It is expected that a significant percentage of the current employees of the EMA will decide not to make the move to the Netherlands. This raises the possibility that new drug approvals in the EU could be delayed as a result.

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Further, in recent years, in order to achieve approvals of and reimbursement for new products and new indications, governmental authorities and payors around the world have increasingly required more clinical trial data than they had in the past, the inclusion of significantly higher numbers of patients in clinical trials, and more detailed analyses of the trials. As a result, despite significant efforts by health authorities such as the FDA to accelerate the development of new drugs, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has in many cases become even more challenging.

Similarly, 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 market share, and loss of revenue and profitability.

There is also the risk that we may fail to identify significant new product candidates for development or potentially disruptive new technologies, and so may fail to take advantage of a potential new wave of innovation.

Our Alcon Division faces similar challenges in bringing new products to market, including both the products and components that have been developed in house, as well as those that have been acquired from third parties. Alcon's Surgical and Vision Care products face medical device development and approval processes that are often similarly as difficult as those faced by our Innovative Medicines Division. For example, the new EU Medical Devices Regulation could bring substantial changes to the way medical device manufacturers bring new products to the European market, including with respect to labelling, technical documentation and quality management systems. Alcon has taken steps to increase its innovation power and the success of its research and development efforts. But these efforts are costly and 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.

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, including those 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 often significantly more costly and complex than those for non-differentiated generic products. In addition, many countries do not yet have fully-developed legislative or regulatory pathways to 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. See also " Intense competition from patented and generic pharmaceuticals companies, as well as failure to obtain marketing exclusivity periods for new generic products, or to successfully develop biosimilars and other differentiated products, may have a material adverse effect on the success of our Sandoz Division," below.

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, data privacy, Good Clinical Practices requirements, data integrity requirements, the fair treatment of patients

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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 a 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 and reimbursement for our products.

Our businesses are operating in an ever more challenging environment, with significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payors. 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 than in the past. These pressures are particularly strong given the increasing demand for healthcare resulting from the aging of the global population and associated increases in non-communicable diseases, and the resulting impact on healthcare budgets. These pressures are further compounded by consolidation among distributors, retailers, private insurers, managed care organizations and other private payors, which can increase their negotiating power, particularly with respect to our generic drugs. In addition, these pressures are augmented by significant controversies and intense publicity about prices for pharmaceuticals that some consider excessive, as well as government investigations and legal proceedings regarding pharmaceutical pricing practices.

As a result, we face numerous cost-containment measures by governments and other payors, including 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, growing pressure on physicians to reduce the prescribing of patented prescription medicines, the imposition or threat of imposition of compulsory licensing or Declarations of Public Interest, and requirements for increased transparency on pricing. For more information on such price controls see "Item 4. Information on the Company Item 4.B Business Overview Innovative Medicines Price Controls." See also " Ongoing consolidation among our distributors and retailers is increasing both the purchasing leverage of key customers and the concentration of credit risk," below, with regard to the impact on pricing of the consolidation among our customers, and " Political and economic instability may have a material adverse effect on our results," below, with regard to the impact of economic conditions on our pricing. These factors may materially affect our ability to achieve an acceptable return on our investments in the development of our products, and may impact our ability to invest in the research and development of new products.

We expect these challenges to continue and potentially to increase in 2018 and following years 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.

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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, we are faced with increasing pressures, including new laws and regulations from around the world, to be more transparent with respect to how we do business, including with respect to our interactions with healthcare professionals and organizations. These laws and regulations include requirements that we disclose payments or other transfers of value made to healthcare professionals and organizations, as well as with regard to the prices for our products.

In addition, we have significant activities in a number of developing countries around the world, both through our own employees, and through third parties retained to assist us. In some of these countries, a culture of compliance with law may not be as fully developed as in other countries.

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, financial position and reputation.

In particular, in recent years, there has been a trend of increasing government investigations, legal proceedings and law enforcement activities against companies and executives operating in our industry, both in the US and in countries around the world. Increasingly, such activities can involve criminal proceedings, and can retroactively challenge practices previously considered to be legal. 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 (including for so-called "pay for delay" patent settlements), securities, insider trading, occupational health and safety, environmental, tax, cybersecurity, data privacy and intellectual property matters. For information on significant legal matters pending against us see "Note 19. Provisions and other non-current liabilities" and "Note 27. Commitments and contingencies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018. See also " Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses," below.

Such proceedings are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments 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, and may lead to civil litigation. As a result, having taken into account all relevant factors, we have in the past and may again in the future enter into major settlements of such claims without bringing them to final legal adjudication by courts or other such bodies, despite having potentially significant defenses against them, in order to limit the risks they pose to our business and reputation. Such settlements may require us to pay significant sums of money, and to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for a period of years.

Any such judgments or settlements, and any accruals that we may take with respect to potential judgments or settlements, 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 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 increase our cost of goods and lead to extended supply disruptions and significant liability.

The manufacture of our products is complex and heavily regulated by governmental health authorities around the world, including the FDA. Whether our products and the related raw materials 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.

Any significant failure by us or our third-party suppliers to comply with these requirements or the health authorities' expectations, may cause us to shut down the production facilities or production lines. Alternately, we may be forced to shut them down by a government health authority, 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. 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.

In addition to these regulatory requirements, the technically complex manufacturing processes required to manufacture many of our products increase the risk of production failures, and can increase the cost of producing our goods. For example, we manufacture and sell a number of sterile products, including oncology products, which require sophisticated environmental controls. In addition, a significant number of our products 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 that 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 involves living plant or animal micro-organisms, the process could be affected by contaminants that could impact those micro-organisms. Further, for our new oncology product *Kymriah,* each dose must be separately produced, using the individual patient's own cells as a basis, without contingencies for production failures. As a result, because the production process for many of our products is so complex and sensitive, the cost of production and the chance of production failures and lengthy supply interruptions is increased.

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 and third party suppliers around the world. However, there can be no guarantee as to the outcome of these efforts, or that we or our third parties suppliers will not face significant manufacturing issues, or that we will successfully manage such issues when they arise. For example, our Sandoz Division has been unable to launch its *Glatopa* 40mg product due to a Warning Letter received from the FDA by our third party supplier with respect to its manufacturing facility.

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In addition, many of our products require a supply of highly specialized raw materials. For some of our products and raw materials, we may rely on a single source of supply. As a result, we are required to plan our production activities well in advance. If we should suffer from product shortages, including as a result of a natural disaster at a production facility, or if we should underestimate market demand for a product, or should fail to accurately predict when the product would be approved for sale, then we may not be able to produce sufficient product to meet demand. Alternately, if we overestimate the quantity or timing of product to be produced, then we may be required to dispose of excess product, which would result not only in the loss of the product, but also the resources spent to produce it.

Further, because our products are intended to promote the health of patients, for some of our products, a 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.

Thus, complex production processes and compliance with regulatory requirements can increase our cost of producing our products, and any significant disruption in the supply of our products could impact our sales, either of which could have a material adverse effect on our business, financial condition or results of operations, as well as our reputation. See also " We may not successfully achieve our goals in transactions or reorganizations," below, with regard to our recent reorganization of our product manufacturing organization, and " Extreme weather events, earthquakes and other natural disasters 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 addition to ordinary market risk, there is a risk that countries could take affirmative 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, countries facing local financial difficulties, including countries experiencing high inflation rates and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Such exchange controls could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries.. See " Political and economic instability may have a material adverse effect on our results," below.

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 expenditures in Swiss francs that are significantly higher than our revenue in Swiss francs, any 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 "Note 28. Financial instruments additional disclosures" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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We may not successfully achieve our goals in transactions or reorganizations.

As part of our strategy, from time to time we acquire and divest products or entire businesses, in order to expand or complement our existing businesses, or to enable us to focus more sharply on our strategic businesses. For example, we recently completed the acquisition of Advanced Accelerator Applications, a radiopharmaceutical company that develops, produces and commercializes molecular nuclear medicines including *Lutathera*, a first-in-class radioligand therapy product for neuroendocrine tumors.

Despite expending significant efforts and resources in this area, we cannot ensure that we will identify products or businesses that are suitable for acquisition. In addition, acquisition activities can be thwarted by governmental regulation, including market concentration limitations, political interference, overtures from competitors for the targeted assets, potentially increasing prices demanded by sellers, and other issues. 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 develop and market acquired products, including products acquired by Alcon, or to integrate the acquired business may not meet expectations, or may otherwise not be successful, as a result of difficulties in retaining key personnel, customers and suppliers, difference in corporate culture, standards, controls, processes and policies, or other reasons. Acquisitions and divestments can also 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. For example, in early 2017, we announced a strategic review of the Alcon Division in order to explore all options to maximize value for our shareholders. Key criteria for a final decision and timing remain continued Alcon sales growth and margin improvement which need to be demonstrated for multiple quarters leading to potential action not likely before the first half of 2019. But there can be no certainty that the strategic review will reach any particular results, or at any particular time, or that it will in fact maximize shareholder value.

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 October 2017, we announced that certain over-the-counter and diagnostic ophthalmic products would be moved from the Innovative Medicines Division to the Alcon Division effective January 1, 2018, where we believe the products will create the most value. We expect this and other similar actions, including our prior move of prescription ophthalmic pharmaceutical products from our Alcon Division to our Innovative Medicines Division, to help 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 such reorganizations may never be fully realized or may take longer to realize than expected. There can be no certainty that the businesses and functions involved will be successfully integrated into the new organizations or that key personnel will be retained. Disruption from the reorganizations may make it more difficult to maintain relationships with customers, employees or suppliers, and the reorganizations may result in the Group not achieving the expected productivity and financial benefits, shortfalls in program oversight, or, potentially, sales declines and lost profits.

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

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

Significant breaches of data security or disruptions of information technology systems and the use of Internet, social media and mobile technologies could adversely affect our business and expose people's personal information.

We are heavily dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support our 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, which can include people's personal information. We are also increasingly seeking to develop technology-based products such as mobile applications and other digital health products that go "beyond the pill" to improve patient welfare in a variety of ways, which could also result in us gathering personal 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 incidents, breakdowns, malicious intrusions, cybercrimes, including State-sponsored cybercrimes, 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 cybersecurity and to business continuity efforts, like many companies, we have experienced certain of these events and expect to continue to experience them in the future, as the external cyber-attack threat only keeps growing. We believe that the information security incidents we have experienced to date have not resulted in significant disruptions to our operations, and have not had a significant adverse effect on our results of operations, or on third parties. However, we may not be able to prevent future breakdowns or breaches in our systems and we may not be able to prevent such events from having a material adverse effect on our business, financial condition, results of operation or reputation.

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

In addition, our routine business operations, including through the use of information technologies such as the Internet, social media, mobile technologies, and technology-based medical devices, increasingly involve our gathering personal information (including sensitive personal information) about patients, vendors, customers, employees, collaborators and others. Breaches of our systems or those of our third-party contractors, or other failures to protect such information, could expose such people's personal information to unauthorized persons. Any such event could give rise to significant potential liability and reputational harm, including potentially substantial monetary penalties. We also make significant efforts to ensure that any international transfers of personal data are done in compliance with applicable law. Any additional restraints 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.

We also use Internet, social media and mobile tools as a means to communicate with the public, including about our products or about the diseases our products are intended to treat. However, such uses create risks, such as the loss of trade secrets or other intellectual property. In addition, there continues to be significant uncertainties as to the rules that apply to such 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

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comply with applicable rules, there is a significant risk that our use of Internet, social media and mobile technologies for such purposes may cause us to nonetheless be found in violation of them.

Our dependence upon information technology, including any breaches of data security, technology disruptions, privacy violations, or other uses of interconnected technologies 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 enforcement actions or liability, including potential government fines, claims for damages, and shareholders' litigation. Any such events could require us to expend significant resources beyond those we already invest to further modify or enhance our protective measures, to remediate any damage, and to enable the continuity of our business. Such events could have a material adverse effect on our business, financial condition, results of operations and reputation.

We may fail to develop or take advantage of transformational technologies and business models.

Rapid progress in digital technologies and in the development of sometimes radical new business models is substantially transforming numerous industries around the world, creating new businesses and new opportunities for revenue and profit, while sometimes quickly rendering established businesses uncompetitive or obsolete. The potential exists for such transformations, both positive and negative, to impact the pharmaceutical industry, and numerous companies from the digital technology and other industries are seeking to enter the healthcare field.

To take advantage of these opportunities, Novartis has embarked upon a digital transformation strategy, with the goal of making Novartis an industry leader in leveraging advanced analytics and other new technologies. As part of this effort, we have created a new role of Chief Digital Officer, reporting directly to the CEO, charged with creating and executing a company-wide digital strategy, to be led by the Executive Committee of Novartis.

In order to reach our goal, we expect to invest substantial resources into efforts to improve the way we use data in drug discovery and development, to improve the ways we engage with patients, doctors and other stakeholders, and to automate business processes. With our commitment to using science-based innovation to deliver better outcomes for patients, together with our expertise and the valuable data we have and continue to amass, we believe that we have an opportunity to transform our business model using digital technologies.

There is no guarantee that our efforts toward a digital transformation will succeed, or that we will successfully transform our business model, or that we will be able to do so at any particular cost or any particular time. In order to succeed, we will be required to encourage a cultural change amongst our employees, attract and retain employees with appropriate skills and mindset, and successfully innovate across a variety of technology fields, while other companies, including both specialized start-up organizations and established technology companies such as IBM, with its Watson project, and Alphabet, with its subsidiary Verily, aggressively move forward in this field.

At the same time, there is a risk that other companies with specialized expertise or business models may enter the healthcare field, potentially disrupting our relationships with patients, healthcare professionals, customers, distributors and suppliers, with unknown potential consequences for us. For example, new entrants may seek to enter the pharmaceutical distribution field.

If we should fail to succeed in our efforts at a digital transformation of our company, then there is a risk that we may fail to create the innovative new products, tools or techniques that such technologies may make possible, or may fail to create them as quickly and efficiently as such technologies may enable. We may also lose opportunities to engage with our stakeholders and to profit from improved business processes, and may lose the resources devoted to these efforts to transform our business. At the same time, should third parties successfully enter the healthcare field with disruptive new technologies or business models, then we potentially may see our business supplanted in whole or in part by these new

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entrants. Any such events could have a material adverse effect on our business, financial condition or results of operations.

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, including, in particular, substantial goodwill and other intangible assets obtained as a result of our acquisitions of Alcon and the oncology assets from GSK. As a result, we may incur significant impairment charges in the future if the fair value of the intangible assets and the groupings of cash generating units containing goodwill 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, intangible assets with an indefinite useful life, acquired research projects not ready for use, 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 2017, for example, we recorded intangible asset impairment charges of $0.7 billion. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the 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 "Note 1. Significant accounting policies" and "Note 10. Goodwill and intangible assets" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Political and economic instability may have a material adverse effect on our results.

Unpredictable political conditions currently exist in various parts of the world, including a backlash in certain areas against free trade, anti-immigrant sentiment, social unrest, the refugee crisis, fears of terrorism and the risk of direct conflicts between nations. In the US, the current presidential administration's opposition to free trade agreements could cause barriers to be raised to international trade, and the elimination of the Affordable Care Act's individual mandate could have a negative impact on individuals' ability to afford health insurance. Similarly, there is a risk that barriers to free trade and the free movement of people may rise in Europe following the UK's "Brexit" vote and the rise of nationalist, separatist and populist sentiment in various countries. And significant conflicts continue in parts of the Middle East, including conflicts involving Saudi Arabia and Iran, and with respect to places such as North Korea. Collectively, such difficult conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties of international transactions.

In addition, local economic conditions may adversely affect the ability of payors, as well as our distributors, customers, suppliers and service providers, to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us. 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 fiscally-challenged government payors, or with third parties with substantial exposure to such payors. See also " Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses," below.

Financial market issues 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, increasing our costs of raising capital. Uncertainties around future central bank and other economic

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policies in the US and EU, as well as high debt levels in certain other countries, could also impact world trade. Sudden increases in economic, currency or financial market volatility in different countries have also 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," above, and " If any of numerous key assumptions and estimates in calculating our pension plan obligations turn out to be different from our actual experience, we may be required to increase substantially our contributions to pension plans as well as the amount we pay toward pension-related expenses in the future," below. See also " Our business is affected by pressures on pricing and reimbursement for our products," above, and "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources Effects of Currency Fluctuations."

There is also a risk that countries facing local financial difficulties, including countries experiencing high inflation rates and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Such exchange controls could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries. See also "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources Condensed Consolidated Balance Sheets," and "Note 14. Trade receivables" and "Note 28. Financial instruments additional disclosures" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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

To the extent that economic and financial conditions directly affect consumers, some of our businesses, including the elective surgical and contact lens businesses of our Alcon Division, may be particularly sensitive to declines in consumer spending. In addition, our Innovative Medicines and Sandoz Divisions may not be immune to declines in consumer spending, particularly given the requirements in certain countries that patients directly pay an increasingly large 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.

At the same time, significant changes and potential future 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.

Separately and collectively, such factors 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.

Our indebtedness could adversely affect our operations.

As of December 31, 2017 we had $23.2 billion of non-current financial debt and $5.3 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 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

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existing debt or incurring new debt on terms that we would consider to be commercially reasonable, if at all.

Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses.

We outsource the performance of certain key business functions to third parties, and invest a significant amount of effort and resources into doing so. Such outsourced functions can include research and development collaborations, manufacturing operations, warehousing and distribution activities, certain finance functions, marketing activities, data management and others. In particular, in many developing countries, we rely heavily on third party distributors and other agents for the sales, marketing and distribution of our products. Similarly, we often obtain the intermediate and raw materials used in the manufacture of our products from third parties located in developing countries.

Our reliance on outsourcing and third parties for certain functions, such as the research and development or manufacturing of our products, may reduce the potential profitability of such products.

In addition, governments and the public are increasingly placing pressure on major corporations, including Novartis, to take responsibility for compliance with human rights and appropriate environmental practices, as well as other actions, of their third party contractors around the world. Examples of this include the Conflict Minerals rule in the US, and the UK Modern Slavery Act.

We place strict contractual requirements on such contractors to comply with law and with our high standards. We also expend significant resources on efforts to screen out inappropriate contractors, to monitor the activities of those we have retained, and to seek their compliance with the law and our expectations. Nonetheless, many of these companies have limited resources, and, in particular, do not have internal compliance resources comparable to those within our organization.

Ultimately, if the third parties fail to meet their obligations to us, 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 or should they act inappropriately in the course of their performance of services for us, there is a risk that we could be held responsible for their acts, that our reputation may suffer, and that penalties may be imposed upon us. Any such failures by third parties could have a material adverse effect on our business, financial condition, results of operations or reputation.

Intense competition from patented and generic pharmaceuticals companies, as well as failure to obtain marketing exclusivity periods for new generic products, or to successfully develop biosimilars and other differentiated products, may have a material adverse effect on the success of our Sandoz Division.

Our Sandoz 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. At the same time, Sandoz faces strong competition from other generic pharmaceutical companies, which aggressively compete for exclusivity periods and for market share of generic products that may be identical to our generic products, including through significant price competition. In the US in 2017, industry-wide price competition among generic pharmaceutical companies significantly hurt Sandoz sales. More generally, such competitive actions by other patented and generic pharmaceutical manufacturers may increase the costs and risks associated with our efforts to introduce generic products, and may delay or entirely prevent their introduction and marketing. Such activities may further limit the prices at which we are able to sell these products and impact our results of operations.

In addition, the 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.

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Sandoz has also invested heavily in the development of biosimilar drugs, despite the fact that regulations concerning their approval, marketing and sale in certain countries, including in the US, are still under development or not entirely clear. If 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 in a cost-efficient manner, or in a manner sufficient to grow our business and replace lost revenue and income" above, with regard to the risks involved in our efforts to develop differentiated generic products, and " Failure to comply with law, legal proceedings and government investigations may have a significant negative effect on our results of operations" above, with regard to the risks of damages involved in our efforts to market generic versions of patented 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 plan expenses and liabilities. These include assumptions used to determine the discount rates we apply to estimated future liabilities and rates of future compensation increases. Assumptions and estimates used by Novartis may differ materially from the actual results we experience in the future, due to changing market and economic conditions, higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, in 2017, 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 nearly 94% of the Group total defined benefit pension obligation, by $0.8 billion. Any differences between our assumptions and estimates and our actual experience could require us to make additional contributions to our pension funds. Further, additional employer contributions might be required if plan funding falls below the levels required by local rules. Either such event could have a material effect on our results of operations and financial condition. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Retirement and Other Post-Employment Benefit Plans" and "Note 24. Post-employment benefits for associates" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018. See also " Political and economic 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.

Our worldwide operations are taxed under the laws of the jurisdictions in which we operate. However, the integrated nature of our worldwide operations can produce conflicting claims from revenue authorities in different countries as to the profits to be taxed in the individual countries, including disputes relating to transfer pricing. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untried, and can be expected to be very lengthy.

In recent years, tax authorities around the world have increased their scrutiny of company tax filings, and have become more rigid in exercising any discretion they may have. As part of this, the Organization for Economic Co-operation and Development (OECD) has proposed a number of tax law changes under

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its Base Erosion and Profit Shifting (BEPS) Action Plans to address issues of transparency, coherence and substance.

At the same time, the European Commission is finalizing its Anti Tax Avoidance Directive, which seeks to prevent tax avoidance by companies and to ensure that companies pay appropriate taxes in the markets where profits are effectively made and business is effectively performed. The European Commission also continues to extend the application of its policies seeking to limit fiscal aid by Member States to particular companies, and the related investigation of the Member States' practices regarding the issuance of rulings on tax matters relating to individual companies.

These OECD and EU tax reform initiatives also need local country implementation, including in our home country of Switzerland, which may result in significant changes to established tax principles. Although we have taken steps to be in compliance with the evolving OECD and EU tax initiatives, and will continue to do so, significant uncertainties remain as to the outcome of these efforts.

In addition, in the United States, the president on December 22, 2017, signed into law the Tax Cuts and Jobs Act of 2017, which includes substantial changes to the US taxation of individuals and businesses. Although the new law substantially decreased tax rates applicable to corporations in the US, we do not yet know what all of the consequences of this new statute will be, including whether the law will have any unintended consequences. In particular, significant uncertainties remain as to how the US government will implement the new law, including with respect to the tax qualification of interest deductions, the concept of a territorial tax regime, royalty payments and cost of goods sold.

In general, such tax reform efforts, including with respect to tax base or rate, transfer pricing, intercompany dividends, cross border transactions, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, will require us to continually assess our organizational structure against tax policy trends, and could lead to an increased risk of international tax disputes and an increase in our effective tax rate, and could adversely affect our financial results.

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

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can potentially be life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of product ineffectiveness or 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 17%, 12% and 7%, respectively, of Group net sales in 2017. The largest trade receivables outstanding were for these three customers, amounting to 14%, 9% and 5%, respectively, of the Group's trade receivables at December 31, 2017. 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, and could include a

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substantial loss of sales and an inability to collect amounts owed to us. Such events 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, including significant efforts to enhance the diversity of our workforce. 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 developing countries could delay or prevent the achievement of major business objectives.

Our future growth will demand talented associates and leaders, yet the market for talent has become increasingly competitive. In particular, emerging growth markets are expected to continue to be an important source of growth, but in many of these countries 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 developing 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. See " Political and economic instability may have a material adverse effect on our results" above.

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

We face intense competition for an increasingly limited pool of qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities, other research institutions, other companies seeking to enter the healthcare space, and companies in other industries. As a result, 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.

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. Information on the Company Item 4.D Property, Plants and Equipment Environmental Matters" and "Note 19. Provisions and other non-current liabilities" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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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 Innovative Medicines Division, and certain of our major Innovative Medicines 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 increase our cost of goods and lead to extended supply disruptions and significant liability," above.

Risks Related To Our ADRs

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

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

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

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

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Item 4. Information on the Company

4.A History and Development of Novartis

Novartis AG

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

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

Novartis is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of healthcare products led by innovative pharmaceuticals. Novartis AG, our Swiss holding company, owns, directly or indirectly, all of our significant operating companies. For a list of our significant operating subsidiaries, see "Note 31. Principal Group subsidiaries and associated companies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Important Corporate Developments 2015-January 2018

2018

January — Novartis announces that it had successfully completed its previously-announced tender offer for all of the then outstanding ordinary shares, including ordinary shares represented by American Depositary Shares (ADSs), of Advanced Accelerator Applications S.A. (AAA). As of the expiration of the offer on January 19, 2018, approximately 97% of the then outstanding fully diluted ordinary shares, including ordinary shares represented by ADSs, were validly tendered. In addition, on January 22, 2018, we commenced a subsequent offering period which will expire on January 31, 2018, unless extended. AAA is a NASDAQ-listed radiopharmaceutical company that develops, produces and commercializes molecular nuclear medicines including *Lutathera* (lutetium (^{177}Lu) oxodotreotide), a first-in-class radioligand therapy product for neuroendocrine tumors.

We announce an exclusive global collaboration between Sandoz and Biocon to develop, manufacture and commercialize multiple biosimilars in immunology and oncology.

Novartis announces that Elizabeth (Liz) Barrett has been appointed CEO Novartis Oncology and a member of the Executive Committee of Novartis (ECN), effective February 1, 2018. Mrs. Barrett succeeds Bruno Strigini who decided to retire from Novartis for personal reasons.

2017

November — Novartis announces an expanded collaboration with Amgen and the Banner Alzheimer's Institute to collaborate on a new Generation Study 2 to assess whether investigational BACE1 inhibitor CNP520 can prevent or delay the symptoms of Alzheimer's disease in a high-risk population.

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October	Novartis announces that it has made significant progress in its ongoing strategic review of the Alcon Division and has examined all options, ranging from retaining the business to a capital markets solution (e.g., an IPO or a spin-off). As part of this, we updated Alcon's strategic plan which confirms that it has the potential to grow sales at or above market while delivering profitability at least in line with the industry. Key criteria for a final decision and timing remain continued Alcon sales growth and margin improvement which need to be demonstrated for multiple quarters leading to potential action not likely before the first half of 2019.
	Novartis announces that its over-the-counter ophthalmic products and certain surgical diagnostic products will transfer from the Innovative Medicines Division to the Alcon Division effective January 1, 2018.
September	Novartis announces a collaboration with UC Berkeley to establish the Novartis-Berkeley Center for Proteomics and Chemistry Technologies.
	Novartis announces that, effective February 1, 2018, Vasant (Vas) Narasimhan, M.D., will succeed Joseph Jimenez as CEO of Novartis, who had indicated his desire to retire after eight years. Robert Kowalski, Pharm.D., Head of Global Regulatory Affairs, will assume ad-interim leadership of our Global Drug Development organization, effective February 1, 2018.
August	Novartis announces that, effective January 1, 2018, Bertrand Bodson has been appointed to the new role of Chief Digital Officer, reporting to the CEO of Novartis. Mr. Bodson is responsible for creating and executing a company-wide digital strategy. As part of this strategy, we plan to improve the ways we use data in drug discovery and development, engage with patients, doctors and other stakeholders, as well as to automate business processes.
June	Novartis announces that it has entered into a clinical research collaboration in which Bristol-Myers Squibb is to investigate the safety, tolerability, and efficacy of *Mekinist* (trametinib) in combination with Opdivo® (nivolumab) and Opdivo® + Yervoy® (ipilimumab) regimen as a potential treatment option for metastatic colorectal cancer in patients with microsatellite stable tumors where the tumors are proficient in mismatch repair (MSS mCRC pMMR).
	Novartis announces a collaboration with IBM Watson Health to explore development of a cognitive solution that uses real-world data and advanced analytical techniques with the aim to provide better insights on the expected outcomes of breast cancer treatment options.
May	Novartis announces the launch of Better Hearts Better Cities, an innovative initiative to address the high rates of high blood pressure in low-income urban communities.
April	Novartis announces an expanded collaboration agreement with Amgen to co-commercialize erenumab (AMG 334) in the US, currently being investigated for the prevention of migraine. This agreement builds on the previously-announced 2015 global collaboration between Novartis and Amgen.
	Novartis announces that it has entered into a clinical trial agreement with Allergan plc to conduct a Phase IIb study, involving the combination of a Novartis FXR agonist and Allergan's cenicriviroc for the treatment of non-alcoholic steatohepatitis (NASH).
	Novartis announces that is has exercised an option to in-license ECF843, a recombinant form of human lubricin from Lubris, LLC, for ophthalmic indications worldwide (outside Europe). This transaction closed and Novartis received its exclusive license on April 21, 2017.
March	Novartis completes euro-denominated bond offerings in an amount equivalent to approximately $2 billion.

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February	Novartis completes a $3 billion bond offering under its US SEC Registration Statement on Form F-3.
January	Novartis announces that it is considering options for the Alcon Division. The review will explore all options, ranging from retaining all or part of the business to separation via a capital markets transaction (e.g., IPO or spin-off), in order to determine how to best maximize value for our shareholders.
	Novartis announces that it is initiating a share buyback of up to $5.0 billion in 2017 under existing shareholder authority.
	Novartis announces that it has entered into a collaboration and option agreement with Ionis Pharmaceuticals, Inc. (Ionis), and its affiliate Akcea Therapeutics, Inc. (Akcea), to license two investigational treatments with the potential to significantly reduce cardiovascular risk in patients suffering from high levels of lipoproteins known as Lp(a) and ApoCIII. In addition, Novartis entered into a stock purchase agreement with Ionis and Akcea. This transaction was completed on February 14, 2017.

2016

December	Novartis announces that it has entered into a definitive agreement for the acquisition of Encore Vision, Inc., a privately-held company focused on the development of UNR844 (formerly EV06), an investigational, first-in-class potentially disease modifying topical treatment for presbyopia. This acquisition was completed on January 20, 2017.
	Novartis announces the signing of an exclusive option, collaboration and license agreement with Conatus Pharmaceuticals Inc., for the global rights to emricasan, an investigational, first-in-class, oral, pan-caspase inhibitor for the treatment of non-alcoholic steatohepatitis (NASH) with advanced fibrosis and cirrhosis of the liver. Novartis exercised the option on May 4, 2017. Novartis obtained an exclusive, worldwide license to develop and commercialize products containing emricasan on July 5, 2017.
	Novartis announces that it has entered into a definitive agreement for the acquisition of Ziarco Group Limited, a privately held company focused on the development of novel treatments in dermatology including ZPL389, a once-daily oral H_4 receptor antagonist in development for atopic dermatitis. This acquisition was completed on January 20, 2017.
November	Novartis announces that it has acquired Reprixys Pharmaceuticals Corporation and SEG101 (crizanlizumab) for reduction of pain crises in sickle cell disease.
September	Novartis completes two euro (EUR) denominated bond offerings totaling EUR 1.75 billion.
June	Novartis announces that it has entered into a collaboration and licensing agreement with Xencor for the development of bispecific antibodies for treating cancer.
	Novartis announces that it will further expand its long-standing partnership with Medicines for Malaria Venture. Novartis will lead the development of antimalarial compound KAF156 with scientific and financial support from Medicines for Malaria Venture in collaboration with the Bill & Melinda Gates Foundation.
May	Novartis announces changes to focus its Pharmaceuticals Division by creating two business units: Novartis Pharmaceuticals and Novartis Oncology. These business units form the Innovative Medicines Division of Novartis. The CEO of each business unit reports directly to the CEO of Novartis and both joined the ECN effective July 1, 2016.
February	Shareholders authorize the Novartis Board of Directors to execute share buybacks within the framework of a seventh share repurchase program that will allow Novartis to repurchase shares for cancellation up to a maximum of CHF 10 billion.

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	Novartis announces that it has entered into an agreement to acquire Transcend Medical, Inc., a privately-held, US-based company focused on developing minimally-invasive surgical devices to treat glaucoma, such as the *CyPass* Micro-Stent. This acquisition was completed on March 23, 2016.
	Novartis announces that it has acquired from Pfizer the rights for the development and commercialization of PF-06438179 (biosimilar infliximab) in the European Economic Area.
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, a new position in the ECN; 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 and strengthening the ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to the Innovative Medicines Division, and by shifting selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division into the Sandoz Division, which changes were operationally completed as of April 1, 2016; and by 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, which changes were operationally completed as of July 1, 2016.
	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 LLC to broaden its portfolio of cancer immunotherapies.
September	Novartis announces the appointment of Dr. James E. Bradner as President of the Novartis Institutes for BioMedical Research and a member of the ECN, effective March 1, 2016, concurrent with the retirement of Dr. Mark C. Fishman, who reached 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.

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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.

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 Innovative Medicines Division and Alcon Division, and the section headed "Development and Registration" included in the description of our Sandoz Division under "Item 4. Information on the Company 4.B Business Overview." For information on other principal capital expenditures and divestitures, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Factors Affecting Comparability of Year-On-Year Results of Operations."

4.B Business Overview

OVERVIEW

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio includes innovative pharmaceuticals and oncology medicines, generic and biosimilar medicines and eye care devices. Our mission is to discover new ways to improve and extend people's lives. Our vision is to be a trusted leader in changing the practice of medicine. Our strategy is to use science-based innovation to deliver better patient outcomes in growing areas of healthcare.

Following the completion of a series of transactions in 2014 and 2015, the Group's continuing operations comprise three global operating divisions, Innovative Medicines, Sandoz and Alcon. We also separately report the results of Corporate activities. The disclosure in this Form 20-F focuses on these continuing operations unless otherwise specified. 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 GSK Consumer Healthcare Holdings Ltd. for the period from March 2015 (the latter reported as an investment in associated companies). We sold on March 2, 2015, our Vaccines Division, excluding our influenza vaccines business, to GSK. Our influenza vaccines business was sold on July 31, 2015 to CSL and our Animal Health Division was sold on January 1, 2015 to Lilly.

Continuing Operations:

Innovative Medicines: Innovative patent-protected prescription medicines

Sandoz: Generic pharmaceuticals and biosimilars

Alcon: Surgical and vision care products

Corporate activities

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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 the areas of each of our three divisions. To maintain our competitive positioning across these segments of the healthcare industry, we place a strong focus on innovating to meet the evolving needs of patients around the world, working to grow our presence in new and emerging markets, and to enhance our productivity to invest for the future and increase returns to shareholders. The financial results of our continuing 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 that are not attributable to specific segments such as certain revenues from intellectual property rights and certain expenses related to post-employment benefits, environmental remediation liabilities, charitable activities, donations and sponsorships.

In January 2018, we announced that Elizabeth (Liz) Barrett has been appointed CEO Novartis Oncology and a member of the ECN, effective February 1, 2018. Mrs. Barrett succeeds Bruno Strigini who decided to retire from Novartis for personal reasons.

In September 2017, we announced that Joseph Jimenez, CEO of Novartis, informed the Board of Directors of his desire to step down as CEO in 2018, after eight years in the position. The Board of Directors has appointed Vasant (Vas) Narasimhan, M.D., Global Head of Drug Development and Chief Medical Officer, as CEO of Novartis, effective February 1, 2018. Dr. Narasimhan is a member of the ECN and joined Novartis in 2005.

In August 2017, we announced that, effective January 1, 2018, Bertrand Bodson has been appointed to the new role of Chief Digital Officer, reporting to the CEO of Novartis. Mr. Bodson is responsible for creating and executing a company-wide digital strategy. As part of this strategy, we plan to improve the ways we use data in drug discovery and development, engage with patients, doctors and other stakeholders, as well as to automate business processes.

In early 2017, we announced a strategic review of our Alcon Division in order to explore all options to maximize value for our shareholders. We have made significant progress in our ongoing strategic review and have examined all options, ranging from retaining the business to a capital markets solution (e.g., an IPO or a spin-off). As part of this, we have updated Alcon's strategic plan which confirms that it has the potential to grow sales at or above market while delivering profitability at least in line with the industry. We have also made significant progress on developing a potential capital markets solution, including financial carve-outs, tax and legal entity structuring, and identifying listing and incorporation locations. Key criteria for a final decision and timing remain continued Alcon sales growth and margin improvement which need to be demonstrated for multiple quarters leading to potential action not likely before first half of 2019.

In addition, we transferred our over-the-counter ophthalmic products and certain surgical diagnostic products (2017 sales of approximately $0.8 billion) from the Innovative Medicines Division to the Alcon Division effective January 1, 2018. Our prescription Ophthalmic medicines business remains with the Innovative Medicines Division. In compliance with IFRS, beginning with our first quarter 2018 results, Novartis will update its segment financial information to reflect this transfer, both for the current and prior years, to aid comparability of year-on-year results.

The Group is organized into three divisions, Innovative Medicines, Sandoz and Alcon, as well as Corporate activities. Our divisions are supported by the following cross-divisional organizational units: Novartis Institutes for BioMedical Research, Global Drug Development and Novartis Operations, which includes Novartis Technical Operations, Novartis Business Services and Novartis Corporate Affairs.

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The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, which conducts drug discovery research and early clinical development trials for our Innovative Medicines Division and also collaborates with our Sandoz Division. Approximately 6,000 full-time equivalent scientists and associates at NIBR are working to discover new medicines for various diseases at sites located in the US, Switzerland and China. For more information about NIBR, see " Innovative Medicines Research and Development Research program," below.

Our Global Drug Development (GDD) organization oversees all drug development activities for our Innovative Medicines Division and the biosimilars portfolio of our Sandoz Division. Development of products for the Surgical and Vision Care franchises within our Alcon Division and of small molecule generics for our Sandoz Division are not included in GDD. GDD works collaboratively with NIBR, Innovative Medicines and Sandoz to execute our overall pipeline strategy and takes an enterprise approach to pipeline portfolio management. GDD incorporates centralized global functions such as Regulatory Affairs and Global Development Operations, as well as Global Development units aligned with our business franchises. GDD was created to increase Group-wide coordination of drug development and to improve resource allocation, technology implementation and process standardization with a goal of further increasing innovation. GDD includes approximately 10,000 full-time equivalent associates worldwide.

Novartis Technical Operations (NTO) was established to centralize management of our manufacturing operations across our Innovative Medicines and Sandoz Divisions, with a goal of further improving efficiency. Manufacturing for Alcon's Surgical and Vision Care franchises continues to be managed by our Alcon Division. NTO is expected to optimize capacity planning and adherence to quality standards, and to 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. NTO includes approximately 26,900 full-time equivalent associates and 68 manufacturing sites across our Innovative Medicines and Sandoz Divisions.

Novartis Business Services (NBS), our shared service organization, delivers integrated solutions to all Novartis divisions and units worldwide. NBS seeks to drive efficiency and effectiveness across Novartis by simplifying and standardizing services across six service domains: human resources, real estate and facility services, procurement, information technology, commercial and medical support activities, and financial reporting and accounting operations. NBS has approximately 10,870 full-time equivalent associates in more than 50 countries. NBS works to leverage the full scale of Novartis to create value across the company and to free up resources to invest in innovation and our product pipeline. NBS continues to transfer the delivery of selected services to its five Global Service Centers in Dublin, Ireland; Hyderabad, India; Kuala Lumpur, Malaysia; Mexico City, Mexico; and Prague, Czech Republic.

In 2017, our Public Affairs and Group Country Management organizations were combined to form Novartis Corporate Affairs to better enable close collaboration among country presidents, unit heads and Public Affairs.

In 2017, Novartis continuing operations achieved net sales of $49.1 billion, while net income from continuing operations amounted to $7.7 billion. Of total net sales from continuing operations, $12.4 billion, or 25%, came from Emerging Growth Markets, and $36.7 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. Research & Development expenditure in 2017 amounted to $9.0 billion.

Headquartered in Basel, Switzerland, our Group companies employed 121,597 full-time equivalent associates as of December 31, 2017. Our products are sold in approximately 155 countries around the world.

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Innovative Medicines Division

Our Innovative Medicines Division researches, develops, manufactures, distributes and sells patented prescription medicines to enhance health outcomes for patients and health-care providers. Innovative Medicines is organized into two global business units: Novartis Oncology and Novartis Pharmaceuticals. Novartis Pharmaceuticals consists of the global business franchises Ophthalmology, Immunology and Dermatology, Neuroscience, Respiratory, Cardio-Metabolic and Established Medicines.

In 2017, the Innovative Medicines Division accounted for $33.0 billion, or 67%, of Group net sales, and for $7.8 billion, or 87%, of Group operating income (excluding Corporate income and expense, net).

Sandoz Division

Our Sandoz Division develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical active substances that are not protected by valid and enforceable third-party patents. Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals. 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 cardiovascular, central nervous system, dermatology, gastrointestinal and hormonal therapies, metabolism, oncology, ophthalmics, pain, and respiratory, as well as finished dosage form anti-infectives sold to third parties. In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

In 2017, Sandoz accounted for $10.1 billion, or 21%, of Group net sales, and for $1.4 billion, or 15%, of Group operating income (excluding Corporate income and expense, net).

Alcon Division

Our Alcon Division researches, develops, manufactures, distributes and sells eye care products. Alcon is a global leader in eye care with product offerings in eye care devices and vision care. Alcon is organized into two global business franchises: Surgical and Vision Care. The Surgical franchise 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. The Vision Care franchise 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 2017, Alcon accounted for $6.0 billion, or 12%, of Group net sales, and for $ 0.2 billion, or 2%, of Group operating income (excluding Corporate income and expense, net).

INNOVATIVE MEDICINES

Overview

Our Innovative Medicines Division is a world leader in offering innovation-driven, patent-protected medicines to patients and physicians. The Innovative Medicines Division researches, develops, manufactures, distributes and sells patented pharmaceuticals, and is composed of two business units: Novartis Oncology and Novartis Pharmaceuticals.

The Novartis Oncology business unit is responsible for the commercialization of products in the areas of oncology and rare diseases. The Novartis Pharmaceuticals business unit is organized into the following global business franchises responsible for the commercialization of various products in their respective

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therapeutic areas: Ophthalmology, Immunology and Dermatology, Neuroscience, Respiratory, Cardio-Metabolic and Established Medicines.

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.

Following an internal reorganization announced on January 27, 2016, nineteen mature products were transferred from our Innovative Medicines Division to the Retail Generics franchise of our Sandoz Division, and Alcon's Ophthalmic Pharmaceuticals products were transferred to our Innovative Medicines Division.

In addition, we transferred our over-the-counter ophthalmic products and certain surgical diagnostic products (2017 sales of approximately $0.8 billion) from the Innovative Medicines Division to the Alcon Division effective January 1, 2018. Our prescription Ophthalmic medicines business remains with the Innovative Medicines Division. In compliance with IFRS, beginning with our first quarter 2018 results, Novartis will update its segment financial information to reflect this transfer, both for the current and prior years, to aid comparability of year-on-year results.

The Innovative Medicines Division is the largest contributor among the divisions of Novartis and reported consolidated net sales of $33.0 billion in 2017, which represented 67% of the Group's net sales.

The product portfolio of the Innovative Medicines Division includes more than 60 key marketed products, many of which are leaders in their respective therapeutic areas.

Innovative Medicines Division Products

The following table and summaries describe certain key marketed products in our Innovative Medicines Division. While we typically seek to sell our marketed products throughout the world, not all products and indications are currently available in every country. In addition, a product may be available under different brand names depending on country and indication. 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 Innovative Medicines Division products.

Selected Marketed Products

Novartis Oncology Business Unit

Business franchise	**Product**	**Common name**	**Indications (vary by country and/or formulation)**	**Formulation**
Oncology	*Afinitor/Votubia* and *Afinitor Disperz/ Votubia* dispersible tablets	everolimus	Postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole Advanced renal cell carcinoma after failure of treatment with VEGF-targeted therapy Advanced neuroendocrine tumors of gastrointestinal, lung or pancreatic origin Renal angiomyolipoma associated with tuberous sclerosis complex (TSC) in patients not requiring immediate surgery Subependymal giant cell astrocytoma associated with TSC in patients not requiring	Tablet Dispersible tablet for oral suspension

immediate surgery
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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
			Adjunctive treatment of patients aged 2 years and older with TSC and refractory seizures	
	Arzerra	ofatumumab	Treatment of patients with chronic lymphocytic leukemia (CLL) who are refractory to fludarabine and alemtuzumab	Intravenous infusion
			In combination with an alkylator-based regimen for the treatment of patients with CLL who have not received prior therapy and are not eligible for fludarabine-based therapy	
			Maintenance/extended treatment for patients with CLL who are in complete or partial response after at least two lines of induction therapy	
			In combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL	
	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 Granules
	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	Capsule
	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 Capsule
			Certain forms of KIT+ gastrointestinal stromal tumors	
			Certain forms of acute lymphoblastic leukemia	
			Dermatofibrosarcoma protuberans	

		Hypereosinophilic syndrome	
		Aggressive systemic mastocytosis	
		Myelodysplastic/myeloproliferative diseases	
Jakavi	ruxolitinib	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	
Kisqali	ribociclib	Postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative locally advanced or metastatic breast cancer as initial endocrine-based therapy in combination with an aromatase inhibitor	Tablet

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Kymriah	tisagenlecleucel	Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse	Suspension for intravenous infusion
	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 or immunoglobulins	Film-coated tablet
			Thrombocytopenia in patients with chronic hepatitis C to allow initiation and maintenance of interferon-based therapy	
			Severe aplastic anemia in patients as first-line therapy (in Japan) and second-line in patients who have had an insufficient response to immunosuppressive therapy (rest of world)	
	Rydapt	midostaurin	In combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by an FDA approved test. *Rydapt* is not indicated as a single-agent induction therapy for the treatment of patients with AML.	Capsule
			For the treatment of adult patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm or mast cell leukemia	
	Sandostatin LAR and *Sandostatin* SC	octreotide acetate	Acromegaly Symptom control for certain forms of neuroendocrine tumors	Vial Ampoule/pre-filled syringe

		Treatment of advanced neuroendocrine tumors of the midgut or of unknown primary origin	
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	Unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by a validated test	Capsule (*Tafinlar*) Tablet (*Mekinist*)
		Metastatic non-small cell lung cancer with BRAF V600E mutation as detected by a validated test	
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/Tyverb	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 an aromatase inhibitor (specifically letrozole in US) for the treatment of patients with hormone sensitive metastatic breast cancer	
			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	
	Votrient	pazopanib	Advanced renal cell carcinoma	Tablet
			Certain types of advanced soft tissue sarcoma after prior chemotherapy	
	Zometa	zoledronic acid	Skeletal-related events from bone metastases	Vial/4mg Ready-to-use
			Hypercalcemia of malignancy	
	Zykadia	ceritinib	Anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer post crizotinib	Capsule

Novartis Pharmaceuticals Business Unit

Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
Ophthalmology	*Azarga/Azorga*	brinzolamide and timolol	Decrease of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient intraocular pressure reduction	Eye drops

Ciprodex	ciprofloxacin and dexamethasone	Treatment of bacterial ear infections	Ear drops
Duotrav	travoprost and timolol	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or who have ocular hypertension	Eye drops
Durezol	difluprednate	Treatment of inflammation and pain associated with ocular surgery	Eye drops
		Treatment of endogenous anterior uveitis	
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	
		Visual impairment due to choroidal neovascularization secondary to other pathologies	
Pataday and *Pazeo*	olopatadine	Signs and symptoms of allergic conjunctivitis	Eye drops
		Ocular itching associated with allergic conjunctivitis	

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Patanol	olopatadine	Signs and symptoms of allergic conjunctivitis	Eye drops
	Simbrinza	brinzolamide and brimonidine tartrate	Decrease of elevated intraocular pressure in adult patients with open-angle glaucoma or hypertension for whom monotherapy provides insufficient intraocular pressure reduction	Eye drops
	Travatan, Travatan Z, Travatan BAK-Free*, Izba*	travoprost	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or who have ocular hypertension	Eye drops
Immunology and Dermatology	*Cosentyx*	secukinumab	Active ankylosing spondylitis	Auto-injector Lyophilized, pre-filled syringe
			Active psoriatic arthritis	
			Moderate-to-severe plaque psoriasis	
			Pustular psoriasis	
	Ilaris	canakinumab	Cryopyrin-associated periodic syndromes	Solution for injection Lyophilized powder for reconstitution for subcutaneous injection
			Tumor necrosis factor-receptor associated periodic syndrome	
			Hyperimmunoglobulin D syndrome / mevalonate kinase deficiency	
			Familial Mediterranean fever	
			Systemic juvenile idiopathic arthritis	
			Gouty arthritis	
			Adult-onset Still's disease	
	Myfortic	mycophenolic acid (as mycophenolate sodium)	Prophylaxis of organ rejection in patients receiving allogeneic renal transplants	Gastro-resistant tablet
	Neoral/Sandimmune	cyclosporine, USP Modified	Prevention of rejection following certain organ transplantation	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/chronic idiopathic urticaria See also, "Respiratory"	Liquid formulation in pre-filled syringe Lyophilized powder in vial
	Zortress/Certican	everolimus	Prevention of organ rejection (heart, liver and kidney)	Tablet Dispersible tablet
Neuroscience	*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
Respiratory	*Onbrez Breezhaler*	indacaterol	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Seebri Breezhaler	glycopyrronium bromide	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Ultibro Breezhaler	indacaterol and glycopyrronium bromide	Chronic obstructive pulmonary disease	Inhalation powder hard capsules
	Xolair	omalizumab	Moderate to severe allergic asthma See also, "Immunology and Dermatology"	Lyophilized powder in vial and liquid formulation in pre-filled syringe
Cardio-Metabolic	*Entresto*	sacubitril and valsartan	Symptomatic chronic heart failure with reduced ejection fraction	Tablet

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
Established Medicines	*Cibacen*	benazepril hydrochloride	Hypertension	Tablet
			Adjunct therapy in congestive heart failure	
			Progressive chronic renal insufficiency	
	Comtan	entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet
	Diovan	valsartan	Hypertension	Tablet Capsule Oral solution
			Heart failure	
			Post-myocardial infarction	
	Diovan HCT/ Co-Diovan	valsartan and hydrochlorothiazide	Hypertension	Tablet
	Eucreas	vildagliptin and metformin	Type 2 diabetes	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	
	Exforge	valsartan and amlodipine besylate	Hypertension	Tablet
	Exforge HCT	valsartan, amlodipine besylate and hydrochlorothiazide	Hypertension	Tablet
	Focalin and Focalin XR	dexmethylphenidate HCl and dexmethylphenidate extended release	Attention deficit hyperactivity disorder	Tablet Capsule
	Galvus	vildagliptin	Type 2 diabetes	Tablet
	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	
Ritalin	methylphenidate HCl	Attention deficit hyperactivity disorder and narcolepsy	Tablet
Ritalin LA	methylphenidate HCl modified release	Attention deficit hyperactivity disorder	Capsule
Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations	Tablet
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
TOBI and *TOBI Podhaler*	tobramycin	Pseudomonas aeruginosa infection in cystic fibrosis	Nebulizer solution (*TOBI)* Inhalation powder (*TOBI Podhaler*)
Trileptal	oxcarbazepine	Epilepsy	Tablet Oral suspension

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Business franchise	Product	Common name	Indications (vary by country and/or formulation)	Formulation
	Tyzeka/Sebivo	telbivudine	Chronic hepatitis B	Tablet Oral solution
	Voltaren/Cataflam	diclofenac sodium/potassium/resinate/free acid	Inflammatory and degenerative forms of rheumatism Post traumatic and post-operative pain, inflammation and swelling Painful and/or inflammatory conditions in gynecology Other painful and/or inflammatory conditions such as renal and biliary colic, migraine attacks and as adjuvant in severe ear, nose and throat infections Post-traumatic inflammation of the tendons, ligaments, muscles, and joints Localized forms of soft-tissue and degenerative rheumatism	Tablet Capsule Oral drops/ oral suspension Ampoule for injection Suppository Gel Powder for oral solution Transdermal patch

Key Marketed Products

Novartis Oncology Business Unit

Oncology

Gleevec/Glivec (imatinib mesylate/imatinib) is a kinase inhibitor approved as a targeted therapy for Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) and to treat patients with metastatic and/or unresectable KIT (CD117) positive (KIT+) gastrointestinal stromal tumors (GIST), and as an adjuvant treatment for certain adult patients following resection of KIT+ GIST. First launched in 2001, *Gleevec/Glivec* is approved in approximately 125 countries. *Gleevec/Glivec* is also approved in the US, EU and Japan to treat Ph+ acute lymphoblastic leukemia, a rapidly progressive form of leukemia. In addition, *Gleevec/Glivec* is 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 80 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.

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 125 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 120 markets, including the US, EU member states, Switzerland and Japan, to treat newly diagnosed patients in the chronic phase. In June

2017, the European Commission approved the inclusion of treatment-free remission data in the "Tasigna Summary of Product Characteristics." Treatment-free remission is the ability to maintain molecular response after stopping tyrosine kinase inhibitor therapy in Ph+ CML patients in chronic phase. In December 2017, the FDA also approved the inclusion of treatment-free remission data in the US label for *Tasigna*.

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Sandostatin SC (octreotide acetate for injection) and *Sandostatin* LAR (octreotide acetate for injectable suspension) are somatostatin analogs indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of 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. *Sandostatin* was first launched in 1988 and is approved in more than 100 countries.

Afinitor/Votubia (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 patients with advanced renal cell carcinoma whose disease has progressed on or after treatment with vascular endothelial growth factor-targeted therapy (in the EU) or after failure of treatment with sunitinib or sorafenib (in the US). *Afinitor* has been approved in more than 110 countries, including the US, EU member states and Japan for the treatment of locally advanced, metastatic or unresectable progressive neuroendocrine tumors (NET) of pancreatic origin. It was approved in the US in February 2016 and the EU in June 2016 for the treatment of patients with progressive, well-differentiated, nonfunctional NET of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic, and is now approved for this indication in more than 45 countries worldwide. In addition, *Afinitor* is approved in 117 countries for postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after recurrence or progression following a non-steroidal aromatase inhibitor (in the EU) or failure of treatment with letrozole or anastrozole (in the US). All oncology indications are approved under the trade name *Afinitor,* in the tablet formulation. Everolimus, under the trade name *Afinitor* in the US and *Votubia* in the EU, is also approved in more than 100 countries to treat patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) not requiring immediate surgery, and in more than 95 countries to treat patients with TSC who have renal angiomyolipoma not requiring immediate surgery. The dispersible tablets for oral suspension formulation is approved for patients with TSC who have SEGA in more than 40 countries including the US (under the trade name *Afinitor Disperz*), EU member states (under the trade name *Votubia*) and Japan (under the trade name *Afinitor*). Dispersible tablets also are approved in more than 30 countries, including EU member states (under the trade name *Votubia*), as adjunctive treatment for patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalization, are associated with TSC. An application is currently under review in the US in support of an indication in select patients with TSC-associated refractory seizures. Everolimus, the active ingredient in *Afinitor/Votubia*, 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.

Exjade and *Jadenu* (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older, as well as chronic iron overload in patients with non-transfusion dependent thalassemia in patients 10 years of age and older. 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,* a dispersible tablet for oral suspension, was first approved in 2005 and is now approved in more than 100 countries, including the US, EU member states and Japan. An oral film-coated tablet formulation that can be swallowed or crushed is approved in the US and Canada under the tradename *Jadenu*. It was approved in the EU and Switzerland under the tradename of *Exjade*. Regulatory applications have been submitted in several other countries. In addition to the film-coated tablet formulation, an additional formulation has also been developed as granules for patients who cannot swallow tablets, using the same composition as the film-coated tablet formulation. *Jadenu* Sprinkle granules were approved in the US, and *Jadenu* granules were approved in Japan in 2017.

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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. *Tafinlar* + *Mekinist* is also approved for the treatment of patients with BRAF V600 mutation positive advanced non-small cell lung cancer, as detected by a validated test, in the US, EU and several other markets. *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 a BRAF and a MEK inhibitor to demonstrate an overall survival benefit over BRAF inhibitor monotherapy after three 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 60 and 40 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., to develop, manufacture, and commercialize trametinib.

Promacta/Revolade (eltrombopag) is a once-daily oral thrombopoietin 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. It is approved in more than 100 countries for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an inadequate response or are intolerant to other treatments. In the US and EU, *Promacta/Revolade* is approved for patients one year and older with chronic ITP who have had an insufficient response to other treatments. *Promacta/Revolade* is approved in Japan for aplastic anemia as first-line therapy and for patients who are refractory to other treatments. It is also approved in 45 countries for the treatment of patients with severe aplastic anemia (SAA) who are refractory to other treatments (in the US for the treatment of patients with SAA who have had an insufficient response to immunosuppressive therapy and in the EU 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). In January 2018, the FDA granted a Breakthrough Therapy designation to *Promacta* for the first line treatment of severe aplastic anemia. In addition, *Promacta/Revolade* is approved in more than 50 countries for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow them to initiate and maintain interferon-based therapy. *Promacta/Revolade* is marketed under a collaboration agreement between Ligand Pharmaceuticals, Inc., and Novartis. *Promacta/Revolade* was acquired from GSK.

Votrient (pazopanib) is a small molecule tyrosine kinase inhibitor that targets a number of growth factors to limit new blood vessel and tumor growth and cell survival. *Votrient* is approved in the US for the treatment of patients with advanced renal cell carcinoma (RCC), and in the EU for first-line treatment of adult patients with advanced RCC 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 advanced RCC 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), and in the EU for the treatment of adult patients with selective subtypes of advanced STS who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo)adjuvant therapy. 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 100 countries worldwide for advanced RCC and in more than 90 countries for advanced STS. *Votrient* was acquired from GSK.

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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 101 countries for patients with myelofibrosis and in more than 75 countries for patients with polycythemia vera, including EU member states and Japan. A five year follow-up of the two pivotal trials, COMFORT-I and COMFORT-II suggests a reduced risk of death for patients randomized to *Jakavi* compared to placebo or best available therapy, respectively. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization in the indications of oncology, hematology and Graft-versus-host disease 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.

Kisqali (ribociclib, formerly LEE011) is a cyclin-dependent kinase inhibitor, a class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6), approved for the treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative locally advanced or metastatic breast cancer as initial endocrine-based therapy in combination with an aromatase inhibitor. *Kisqali* has been approved in approximately 45 countries, including in the US in March 2017 and in the EU member states in August 2017. In May 2017, the FDA also approved the *Kisqali Femara* Co-Pack (ribociclib tablets; letrozole tablets). *Kisqali* was developed by the Novartis Institutes for BioMedical Research under a research collaboration with Astex Pharmaceuticals.

Rydapt (midostaurin, formerly PKC412) is an oral, multi-targeted therapy, a type of treatment that interferes with certain pathways that are involved in the growth, progression and spread of cancer. In April 2017, the FDA approved *Rydapt* in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by an FDA approved test. *Rydapt* is not indicated as a single-agent induction therapy for the treatment of patients with AML. *Rydapt* is also approved in the US for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN) or mast cell leukemia. In September 2017, the EMA approved *Rydapt* in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for adults in complete response followed by *Rydapt* single agent maintenance therapy, for adults with newly diagnosed AML who are FLT3 mutation-positive. It is also approved in the EU for use as monotherapy for the treatment of adults with ASM, SM-AHN or mast cell leukemia. Indications vary by country and not all indications are available in every country. *Rydapt* is the first targeted treatment for newly diagnosed FLT3-mutated AML and the first approved treatment for advanced systemic mastocytosis.

Kymriah (tisagenlecleucel, formerly CTL019) suspension for intravenous infusion is a CD19-directed genetically modified autologous chimeric antigen receptor T (CAR-T) cell therapy. *Kymriah* is approved in the US for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse.

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Novartis Pharmaceuticals Business Unit

Ophthalmology

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factor A (VEGF-A), a key mediator of intraocular neovascularization. *Lucentis* is an anti-VEGF therapy specifically designed for the eye, minimizing systemic exposure. *Lucentis* is approved for six indications: neovascular (wet) 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), visual impairment due to choroidal neovascularization secondary to pathologic myopia (myopic CNV) and visual impairment due to choroidal neovascularization (CNV) associated with causes other than nAMD or secondary to pathologic myopia (PM). EC approval in visual impairment due to CNV associated with causes other than nAMD or secondary to PM was received in 2016, and this indication is now approved in 86 countries including the countries of the EU and Switzerland. Further submissions for this indication have been filed in 29 countries. The *Lucentis* pre-filled syringe has now launched in 33 countries. *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. For further information see "Note 26. Transactions with related parties Genentech/Roche" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Travatan (travoprost), *Travatan Z* (travoprost) and *Duotrav* (travoprost/timolol) are indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or who have ocular hypertension. Single agent travoprost products (*Travatan*, *Travatan Z*, *Travatan* BAK-Free and *Izba*) are prescribed as first-line agents and are marketed in more than 140 countries, including the US, countries of the EU, Canada and China. *Duotrav* is a fixed-dose combination solution of the prostaglandin analog travoprost with the beta-blocker timolol, and is approved as a second-line treatment in adults for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogs. *Duotrav* is currently marketed in more than 140 countries, including countries of the EU, Canada and China.

Immunology and Dermatology

Cosentyx (secukinumab) is a fully human monoclonal antibody that selectively neutralizes circulating interleukin 17A (IL-17A). IL-17A is a cytokine involved in the pathogenesis of psoriasis, ankylosing spondylitis and psoriatic arthritis. *Cosentyx* has been approved in over 75 markets, including the US, Japan and the countries of the EU, for the treatment of moderate-to-severe plaque psoriasis. *Cosentyx* is also approved in more than 65 countries for the treatment of adults with ankylosing spondylitis and psoriatic arthritis, including the US and the countries of the EU. *Cosentyx* is also approved in Japan for the treatment of pustular psoriasis, and both psoriasis vulgaris and psoriatic arthritis in adults who are not adequately responding to systemic therapies (except for biologics). Phase III 5-year data presented at a European medical congress in September 2017 showed high and long-lasting skin clearance in patients with moderate-to-severe plaque psoriasis with a continued favorable safety profile of *Cosentyx* sustained over the 5-year treatment period. *Cosentyx* in ankylosing spondylitis and psoriatic arthritis showed sustained improvements in signs and symptoms of both conditions in up to 80% of patients at three and four years respectively, as well as pain relief being rapid and sustained out to two years in both psoriatic arthritis and ankylosing spondylitis patients. Data presented at a US medical congress in November 2017 showed that almost 80% of ankylosing spondylitis patients have no radiographic progression of the spine at four years. In 2017, a label update for *Cosentyx* was also approved in the EU based on data showing long-term superiority over Stelara® (ustekinumab) in moderate-to-severe plaque psoriasis, along with efficacy in the treatment of moderate-to-severe scalp psoriasis, one of the most difficult to treat forms of the disease.

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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.

Xolair (omalizumab) is a recombinant, DNA-derived, humanized IgG1K monoclonal antibody. *Xolair* is designed to block IgE, which limits the release of mediators in the early and late phases of the allergic inflammatory cascade. *Xolair* is currently approved in the EU, Switzerland and more than 80 countries as a treatment for chronic spontaneous urticaria (CSU), also known as chronic idiopathic urticaria (CIU). CSU is a skin condition that appears spontaneously and causes persistent hives and/or painful deeper swelling of the skin for six weeks or more. The approval for CSU in the EU includes use 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. In 2017, new data demonstrated retreatment efficacy with *Xolair* in CSU patients after a treatment pause. 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. For further information see "Note 26. Transactions with related parties Genentech/Roche" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Ilaris (canakinumab) is a selective, high-affinity fully human monoclonal antibody that inhibits interleukin-1β (IL-1β), a key cytokine in the inflammatory pathway, by blocking the action of IL-1β for a sustained period of time. *Ilaris* is approved in more than 70 countries as a treatment for various inflammatory conditions, especially for adults and children with cryopyrin-associated periodic syndrome, systemic juvenile idiopathic arthritis, and the symptomatic treatment of refractory acute gouty arthritis. In 2016, *Ilaris* received approval for patients with adult-onset Still's disease in Europe, and for three rare and distinct types of Periodic Fever Syndromes, also known as Hereditary Periodic Fevers, in the US and Japan. *Ilaris* was approved in the EU in February 2017 for the same three Periodic Fever Syndromes.

Neuroscience

Gilenya (fingolimod) is an oral disease-modifying therapy approved to treat relapsing forms of multiple sclerosis. *Gilenya* has a reversible lymphocyte redistribution effect targeting both focal and diffuse central nervous system damage caused by multiple sclerosis (MS). 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* impacts four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. *Gilenya* is currently approved in more than 80 countries around the world. *Gilenya* is licensed from Mitsubishi Tanabe Pharma Corporation.

Respiratory

Xolair (omalizumab) is approved for the treatment of moderate-to-severe, or severe, persistent allergic asthma for children (age 6 and older) and adults in more than 90 countries, including the US since 2003, the EU since 2005, and Japan since 2009. *Xolair* is provided as lyophilized powder for resolution, and in addition as liquid formulation in a pre-filled syringe in most European countries. See also, *Xolair* in "Immunology and Dermatology" above. 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. For further information see "Note 26. Transactions with related parties Genentech/Roche" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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Cardio-Metabolic

Entresto (sacubitril/valsartan) is a first-in-class angiotensin receptor/neprilysin inhibitor indicated for the treatment of symptomatic 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 in the US and in the EU in 2015. *Entresto* is now approved in more than 95 countries, and launched in more than 50 countries. Both European Society of Cardiology heart failure guidelines and US heart failure guidelines have given a class I recommendation, the strongest class of recommendation, for the use of sacubitril/valsartan in patients with HFrEF.

Established Medicines

Galvus (vildagliptin), an oral DPP-4 inhibitor, and *Eucreas*, a single-pill combination of vildagliptin and metformin, are indicated for the treatment of type 2 diabetes. The products were first approved in 2007. *Galvus* is currently approved in more than 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 approval in the EU for expanded use as a second-line monotherapy for type 2 diabetes patients who cannot take metformin. In 2012, the EU approved the use of *Galvus* 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 use of vildagliptin in triple combination with metformin and a sulphonylurea is also approved in the EU for the treatment of type 2 diabetes when diet and exercise plus dual therapy with vildagliptin and metformin do not provide adequate glycemic control. *Galvus* monotherapy indication was approved in China in 2015. *Eucreas* was approved in Japan in 2015 under the name *Equmet* as the first single-pill combination metformin/DPP-4 inhibitor approved in that country.

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.

Diovan (valsartan), together with *Diovan HCT/Co-Diovan* (valsartan and hydrochlorothiazide), is an angiotensin II receptor blocker (ARB). *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 80 countries for heart failure and for heart attack survivors. First launched in 1997, *Diovan HCT/Co-Diovan* is approved in more than 100 countries worldwide.

Voltaren/Cataflam (diclofenac sodium/potassium/resinate/free acid/diethylamine) 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 is marketed by the Innovative Medicines Division in a wide variety of dosage forms including tablets, capsules, drops, suppositories, ampoules and topical therapy. Our Sandoz Division also markets generic versions of the product in various countries. In addition, we have licensed the *Voltaren* trademarks to our consumer healthcare joint venture with GSK to be

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used in the marketing of the topical and low dose oral forms of *Voltaren* as over-the-counter products.

Exelon capsules/oral solution (rivastigmine tartrate) and *Exelon* Patch (rivastigmine transdermal system) are cholinesterase inhibitors indicated for the treatment of Alzheimer's disease (AD) dementia and Parkinson's disease (PD) dementia. They are the oral and transdermal formulations, respectively, of the cholinesterase inhibitor rivastigmine. *Exelon* capsules have been available since 1997 to treat mild-to-moderate AD dementia and are approved in more than 80 countries. In 2006, *Exelon* capsules 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 formulation *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 ($15cm^2$) 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 of *Exelon* Patch ($15cm^2$) has been approved in more than 70 countries. The severe indication has now been approved in more than 10 countries.

Compounds in Development

The following table and paragraph summaries provide an overview of the key Innovative Medicines Division projects currently in the Confirmatory Development stage, including projects seeking to develop potential uses of new molecular entities as well as potential additional indications or new formulations for already marketed products. Changes to the "Selected Development Projects" table are highlighted in the table below entitled "Projects Added to and Subtracted from the Development Table Since 2016."

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.

The year that each project entered the current phase of development disclosed below reflects the year in which the decision to enter the phase was made. This may be different from the year in which the first patient received the first treatment in the related clinical trial. A reference to a project being in registration means that an application has been filed with a health authority for marketing approval.

Selected Development Projects

Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
ABL001	asciminib	BCR-ABL inhibitor	Chronic myeloid leukemia, 3rd line	Oncology	Oral	2017	2020/III
			Chronic myeloid leukemia, 1st line	Oncology	Oral	2017	≥2022/II
ACZ885	canakinumab	Anti-interleukin-1β monoclonal antibody	Secondary prevention of cardiovascular events	Cardio-Metabolic	Subcutaneous injection	2017	US/EU (registration)[(1)]
				Oncology		2017	2021/III

2nd line non-small cell lung cancer		Subcutaneous injection		
1st line non-small cell lung cancer	Oncology	Subcutaneous injection	2017	≥2022/III
Adjuvant non-small cell lung cancer	Oncology	Subcutaneous injection	2017	≥2022/III

(1) Submissions pending acceptance by FDA and EMA.

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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**
Afinitor/Votubia	everolimus	mTOR inhibitor	Tuberous sclerosis complex seizures	Oncology	Oral	2017	EU (approved) US (registration)
AMG 334	erenumab	Selective CGRP receptor antagonist	Prophylaxis of migraine	Neuroscience	Subcutaneous injection	2017	US/EU (registration)
Arzerra	ofatumumab	Anti-CD20 monoclonal antibody	Refractory indolent non-Hodgkin's lymphoma	Oncology	Intravenous infusion	2010	2020/III
BAF312	siponimod	Sphingosine-1-phosphate receptor modulator	Secondary progressive multiple sclerosis	Neuroscience	Oral	2012	2018/III
BYL719	alpelisib	PI3Kα inhibitor	Hormone receptor-positive, HER2-negative advanced breast cancer (postmenopausal women), 2nd line (+ fulvestrant)	Oncology	Oral	2015	2018/III
BYM338	bimagrumab	Inhibitor of activin receptor Type 2	Hip fracture recovery	Neuroscience	Intravenous infusion	2012	≥2022/II
			Sarcopenia	Neuroscience	Intravenous infusion	2014	≥2022/II
CAD106	amilomotide	Beta-amyloid-protein therapy	Alzheimer's disease	Neuroscience	Intramuscular injection	2009	≥2022/II/III
CFZ533	TBD	Blocking, non-depleting, anti-CD40 monoclonal antibody	Solid organ transplantation	Immunology and Dermatology	Intravenous infusion	2017	≥2022/II
CNP520	TBD	BACE inhibitor	Alzheimer's disease	Neuroscience	Oral	2016	≥2022/II/III
Cosentyx	secukinumab	Anti-interleukin-17 monoclonal antibody	Non-radiographic axial spondyloarthritis	Immunology and Dermatology	Subcutaneous injection	2015	2019/III
			Psoriatic arthritis head-to-head study vs. Humira® (adalimumab)	Immunology and Dermatology	Subcutaneous injection	2015	2020/III
			Ankylosing spondylitis head-to-head study vs. proposed Sandoz biosimilar adalimumab	Immunology and Dermatology	Subcutaneous injection	2015	≥2022/III
CTL019 (approved in the	tisagenlecleucel	CD19-targeted chimeric antigen receptor T-cell	Pediatric/young adult acute	Oncology	Intravenous infusion	2017	US (approved) EU (registration)

US as *Kymriah*)		immunotherapy	lymphoblastic leukemia				
			Relapsed/refractory diffuse large B-cell lymphoma	Oncology	Intravenous infusion	2017	US/EU (registration)
			Relapsed/refractory follicular lymphoma	Oncology	Intravenous infusion	2017	2020/II
			Chronic lymphocytic leukemia	Oncology	Intravenous infusion	2017	2021/III
			Relapsed/refractory diffuse large B-cell lymphoma in 1st relapse	Oncology	Intravenous infusion	2017	≥2022/II
			Relapsed/refractory diffuse large B-cell lymphoma (+ pembrolizumab)	Oncology	Intravenous infusion	2017	≥2022/III
ECF843	TBD	Boundary lubricant	Dry eye	Ophthalmology	Eye drops	2017	≥2022/II
EGF816	TBD	EGFR mutation modulation	Non-small cell lung cancer	Oncology	Oral	2017	2020/III
EMA401	olodanrigan	Angiotensin II type 2 receptor antagonist	Peripheral neuropathic pain	Neuroscience	Oral	2015	2021/II
Entresto	valsartan and sacubitril (as sodium salt complex)	Angiotensin receptor/ neprilysin inhibitor	Chronic heart failure with preserved ejection fraction	Cardio-Metabolic	Oral	2012	2019/III
			Post-acute myocardial infarction	Cardio-Metabolic	Oral	2015	2020/III
Gilenya	fingolimod	Sphingosine-1-phosphate receptor modulator	Pediatric multiple sclerosis	Neuroscience	Oral	2017	US/EU (registration)

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Project/Product	Common name	Mechanism of action	Potential indication/ Disease area	Business franchise	Formulation/ Route of administration	Year Project Entered Current Development Phase	Planned filing dates/Current phase
HDM201	TBD	p53-HDM2 inhibitor	Acute myeloid lymphoma	Oncology	Oral	2017	≥2022/II
INC280	capmatinib	c-MET inhibitor	Non-small cell lung cancer	Oncology	Oral	2014	2019/III
			Non-small cell lung cancer EGFR mutation	Oncology	Oral	2016	≥2022/II
Jakavi	ruxolitinib	JAK1/JAK2 inhibitor	Acute graft-versus-host disease	Oncology	Oral	2016	2020/III
			Chronic graft-versus-host disease	Oncology	Oral	2016	2020/III
KAE609	cipargamin	PfATP4 inhibitor	Malaria	Established Medicines	Oral	2012	≥2022/II
KAF156	TBD	Imidazolopiperazines derivative	Malaria	Established Medicines	Oral	2014	≥2022/II
Kisqali	ribociclib	CDK4/6 inhibitor	Hormone receptor-positive, HER2-negative advanced breast cancer (postmenopausal women), 1st/2nd line (+ fulvestrant)	Oncology	Oral	2014	2018/III
			Hormone receptor-positive, HER2-negative advanced breast cancer (premenopausal women), 1st line, (+ tamoxifen + goserelin or NSAI + goserelin)	Oncology	Oral	2015	2018/III
			Hormone receptor-positive, HER2-negative breast cancer (adjuvant)	Oncology	Oral	2016	≥2022/III
LAM320	clofazimine	Mycobacterial DNA binding	Multi-drug resistant tuberculosis	Established Medicines	Oral	2016	2018/III
LCI699	osilodrostat	Cortisol synthesis inhibitor	Cushing's disease	Oncology	Oral	2014	2018/III

LHW090	TBD	Neprilysin inhibitor	Resistant hypertension	Cardio-Metabolic	Oral	2017	≥2022/II
LIK066	TBD	SGLT 1/2 inhibitor	Weight loss	Cardio-Metabolic	Oral	2016	≥2022/II
LJN452	tropifexor	FXR agonist	Non-alcoholic steatohepatitis	Immunology and Dermatology	Oral	2015	≥2022/II
LMI070	branaplam	SMN2 RNA splicing modulator	Spinal muscular atrophy	Neuroscience	Oral	2017	2021/III
LOU064	TBD	BTK inhibitor	Chronic spontaneous urticaria	Immunology and Dermatology	Oral	2017	≥2022/II
Lucentis	ranibizumab	Anti-VEGF monoclonal antibody fragment	Retinopathy of prematurity	Ophthalmology	Intravitreal injection	2014	2018/III
MAA868	TBD	Factor XI inhibitor	Stroke prevention in atrial fibrillation	Cardio-Metabolic	Subcutaneous injection	2017	≥2022/II
MTV273	TBD	BCMA-targeted chimeric antigen receptor T-cell immunotherapy	Multiple myeloma	Oncology	Intravenous infusion	2017	2021/I
OMB157	ofatumumab	Anti-CD20 monoclonal antibody	Relapsing multiple sclerosis	Neuroscience	Subcutaneous injection	2015	2019/III
PDR001	spartalizumab	Anti PD-1 monoclonal antibody	Malignant melanoma (w/ *Tafinlar* + *Mekinist*)	Oncology	Intravenous infusion	2017	2019/III
			Endocrine neoplasm	Oncology	Intravenous infusion	2017	2019/III
			Malignant melanoma	Oncology	Intravenous infusion	2017	2021/II
Promacta/ Revolade	eltrombopag	Thrombopoietin receptor agonist	Severe aplastic anemia, 1st line	Oncology	Oral	2016	2018/III
QAW039	fevipiprant	DP2 antagonist (CRTH2 antagonist)	Asthma	Respiratory	Oral	2015	2020/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**
QBW251	TBD	CFTR potentiator	Chronic obstructive pulmonary disease	Respiratory	Oral	2017	≥2022/II
QGE031	ligelizumab	High affinity anti-IgE monoclonal antibody	Chronic spontaneous urticaria/ chronic idiopathic urticaria	Immunology and Dermatology	Subcutaneous injection	2014	2021/II
QMF149	indacaterol, mometasone furoate (in fixed dose combination)	Long-acting beta2-adrenergic agonist and inhaled corticosteroid	Asthma	Respiratory	Inhalation	2015	2019/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	2019/III
RTH258	brolucizumab	Anti-VEGF single-chain antibody fragment	Neovascular age-related macular degeneration	Ophthalmology	Intravitreal injection	2014	2018/III
			Diabetic macular edema	Ophthalmology	Intravitreal injection	2017	2020/III
Rydapt	midostaurin	Signal transduction inhibitor	Acute myeloid leukemia (FLT3 wild type)	Oncology	Oral	2016	≥2022/III
SEG101	crizanlizumab	P-selectin inhibitor	Sickle cell disease	Oncology	Intravenous infusion	2016	2019/III
Signifor LAR	pasireotide	Somatostatin analogue	Cushing's disease	Oncology	Long-acting release/ intramuscular injection	2017	EU (approved) US (registration)
Tafinlar + *Mekinist*	dabrafenib + trametinib	BRAF inhibitor + MEK inhibitor	BRAF V600+ melanoma (adjuvant)	Oncology	Oral	2017	US (approved) EU (registration)
UNR844	TBD	Reduction of disulfide bonds	Presbyopia	Ophthalmology	Eye drops	2017	2021/II
VAY736	TBD	Anti-BAFF (B-cell activating factor)	Autoimmune hepatitis	Immunology and Dermatology	Subcutaneous injection	2016	2021/II

		monoclonal antibody					
			Primary Sjogren's syndrome	Immunology and Dermatology	Subcutaneous injection	2015	≥2022/II
VAY785	emricasan	Pan-caspase inhibitor	Nonalcoholic steatohepatitis	Immunology and Dermatology	Oral	2017	≥2022/II
Xolair	omalizumab	Anti-IgE monoclonal antibody	Nasal polyps	Respiratory	Subcutaneous injection	2017	2020/III
ZPL389	TBD	Histamine H_4 receptor antagonist	Atopic dermatitis	Immunology and Dermatology	Oral	2017	2021/II

Key Development Projects

ABL001 (asciminib) is a potent and specific inhibitor of the protein BCR-ABL. It binds to a distinct region of the protein, resulting in a mechanism of action that is different compared to tyrosine kinase inhibitors (TKIs) approved to treat Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). Because of its unique receptor binding site, the compound may have the potential to be prescribed in combination with TKIs approved to treat Ph+ CML. Clinical trials investigating ABL001 are ongoing. A Phase III clinical study was initiated in October 2017 comparing the efficacy of ABL001 versus bosutinib in patients with CML-CP who are either resistant or intolerant to two prior TKIs.

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ACZ885 (canakinumab) was first approved in 2009 for cryopyrin-associated periodic syndromes as *Ilaris*. In 2017 data from CANTOS, a Phase III study evaluating quarterly injections of ACZ885 in people with a prior heart attack and inflammatory atherosclerosis, was presented at the European Society of Cardiology Congress and published simultaneously in The New England Journal of Medicine and The Lancet. CANTOS met its primary endpoint with a statistically significant 15% reduction of major adverse cardiovascular events (MACE) in people with a prior heart attack and inflammatory atherosclerosis who were treated with 150mg of ACZ885 in addition to standard of care including lipid-lowering therapy. This effect was driven by 24% relative reduction in risk of heart attack. A non-significant 10% reduction in risk of cardiovascular death was also observed. A sub-group of study participants, in the 150 mg arm, whose inflammation was reduced below the median high-sensitivity C-reactive protein level, measured at three months after one dose of treatment, saw a 27% relative risk reduction on the primary MACE endpoint. A review of a blinded, pre-planned oncology safety analysis revealed a 77% reduction in lung cancer mortality and 67% reduction in lung cancer cases in patients treated with 300 mg of ACZ885. Novartis is discussing the CANTOS study findings with health authorities and plans to submit the cardiovascular data for regulatory approval, as well as evaluate the lung cancer findings in additional Phase III confirmatory studies.

AMG 334 (erenumab) is a fully human monoclonal antibody designed to block the calcitonin gene-related peptide (CGRP) receptor, which is believed to play a critical role in mediating the incapacitating pain of migraine. Data from a pivotal Phase II study of erenumab presented in September 2017 at the Congress of the International Headache Society showed reduced monthly migraine days in patients with chronic migraine for whom previous preventive treatments have failed. In these patients, erenumab cut the average number of migraine days by at least five days and up to a week per month, depending on treatment dose. New data was also presented at the September 2017 Congress of the International Headache Society assessing the safety of erenumab 140 mg intravenous in a cardiovascular population with stable angina who are at increased risk for myocardial ischemia. Results of this study showed that inhibition of the CGRP receptor with erenumab had no impact on exercise capacity as measured by an exercise stress test. In January 2018, Novartis announced topline results from the Phase IIIb LIBERTY study of erenumab. The study met its primary endpoint with significantly more patients taking erenumab experiencing at least a 50% reduction from baseline in their monthly migraine days as compared to placebo. The trial assessed patients who tried and failed two to four previous preventive medications due to lack of efficacy or intolerable side effects. LIBERTY is the first migraine prevention trial of its kind conducted specifically in patients who have tried multiple therapies without success, and are in need of additional treatment options. In 2017 Novartis submitted AMG 334 to the EMA for migraine prophylaxis. Amgen Inc.'s filing for the same indication was also accepted by the FDA in July 2017. If approved, Novartis and Amgen plan to co-commercialize erenumab in the US. Amgen has exclusive commercialization rights in Japan, and Novartis has exclusive commercialization rights in the rest of the world. The companies plan to continue global co-development.

Arzerra (ofatumumab) is a fully 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. *Arzerra* is approved in more than 60 countries worldwide as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab, and is also approved for other indications in CLL in the US and EU. A Phase III trial is underway to investigate ofatumumab in refractory indolent non-Hodgkin's lymphoma. Novartis is also investigating ofatumumab (disclosed as OMB157) in two Phase III studies for relapsing multiple sclerosis. *Arzerra* is marketed under a license agreement between Genmab A/S and Novartis.

BAF312 (siponimod) is an oral, second-generation sphingosine 1-phosphate receptor modulator under development for the treatment of secondary progressive multiple sclerosis (SPMS). BAF312

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binds selectively to the sphingosine 1-phosphate receptor subtypes 1 and 5, and distributes effectively to the brain where it may impact central nervous system inflammation and repair mechanisms. Results from the EXPAND Phase III study, evaluating efficacy and safety for SPMS, demonstrated that BAF312 reduced three- and six-month confirmed disability progression against placebo, with a safety profile similar to fingolimod. New data from the Phase III EXPAND study presented at the October 2017 joint meeting of the European and American Committees for Treatment and Research in Multiple Sclerosis demonstrated the effects of BAF312 on magnetic resonance imaging lesions and brain shrinkage in SPMS. Effects of BAF312 on disability progression in patients without on-study relapses were also presented. Results from EXPAND have been submitted for peer review publication. Novartis is planning to file BAF312 in the US and EU in 2018 for SPMS. If approved, label content will be subject to negotiation with regulatory authorities, but is expected to reflect the unique SPMS population studied in the EXPAND trial.

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 BYL719 than those without the mutation across a broad range of different cancers. BYL719 is being studied in the Phase III SOLAR-1 trial in combination with fulvestrant in men and postmenopausal women with hormone receptor-positive advanced breast cancer who received prior treatment with aromatase inhibitor and a Phase II trial to determine the maximum tolerated dose in combination with fulvestrant in PIK3CA mutated estrogen receptor-positive breast cancer patients.

Cosentyx (secukinumab) is a fully human monoclonal antibody that selectively neutralizes IL-17A. *Cosentyx* is in Phase III development in non-radiographic axial spondyloarthritis. We expect results from this trial in 2019. *Cosentyx* is also in a Phase III head-to-head clinical trial in psoriatic arthritis against Humira® (adalimumab) and a Phase III head-to-head clinical trial in ankylosing spondylitis against the proposed biosimilar adalimumab in development by Sandoz.

CTL019 (tisagenlecleucel, approved in the US as *Kymriah*) is a CD19-directed genetically modified autologous chimeric antigen receptor T (CAR-T) cell therapy that uses the patient's own immune system to fight certain types of cancer. CARs are engineered proteins that enable a patient's own T cells to seek out specific 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. In August 2017, the FDA approved CTL019 as *Kymriah* for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. *Kymriah* is also currently under regulatory review in the US for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), the most common type of non-Hodgkin lymphoma. In the EU, the EMA is reviewing the CTL019 Marketing Authorization Application for the treatment of adult patients with relapsed/refractory DLBCL ineligible for autologous stem cell transplantation and for pediatric and young adult patients with relapsed/refractory ALL. At the American Society of Hematology Annual Meeting in December 2017, Novartis presented data from the primary analysis of the pivotal, Phase II JULIET trial that CTL019 sustained complete responses at six months in adults with relapsed/refractory DLBCL. CTL019 is also expected to enter Phase II development for adult patients with relapsed/refractory follicular lymphoma who have failed at least two prior systemic therapies. A Phase III study in second-line use in adult patients with DLBCL after first relapse is also being planned. Clinical trials in these patient populations are anticipated to begin in 2018. In January 2018, the FDA granted Priority Review for *Kymriah* for the treatment of adults with relapsed or refractory DLBCL who are ineligible for or relapse after autologous stem cell transplant (ASCT). Also in January 2018, the EMA granted accelerated assessment for CTL019 for the treatment of children and young adults with relapsed or refractory B-cell acute lymphoblastic

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leukemia, and for adult patients with relapsed or refractory DLBCL who are ineligible for ASCT. Novartis and the University of Pennsylvania's Perelman School of Medicine, which developed this CD19-directed CAR T cell therapy, have a global collaboration to research, develop and commercialize CAR-T therapies for the investigational treatment of cancers.

EMA401 (olodanrigan) is a novel angiotensin II type 2 receptor (AT_2R) antagonist. Targeting AT_2R is an emerging approach to neuropathic pain treatment. AT_2R antagonists block the pain signaling pathways in the peripheral nervous system. The first Phase II study to assess the potential of EMA401 in peripheral neuropathic pain was initiated in 2017, with the second Phase II study planned to start in 2018.

Entresto (sacubitril/valsartan) is a first-in-class angiotensin receptor/neprilysin inhibitor approved and marketed for the treatment of chronic heart failure with reduced ejection fraction. In addition, Novartis is conducting multiple studies of *Entresto* as part of the FortiHFy clinical program. This includes two large outcome studies. The first, PARAGON-HF, a Phase III trial of *Entresto* in patients with chronic heart failure with preserved ejection fraction, has completed enrollment with results expected in 2019. Novartis continues recruitment in PARADISE-MI, a Phase IIIb trial for patients at high risk for heart failure after an acute myocardial infarction, with results expected in 2020.

Gilenya (fingolimod, formerly FTY720) is a sphingosine 1-phosphate receptor modulator approved for the treatment of relapsing forms of multiple sclerosis in adults as *Gilenya*. Results from the Phase III PARADIGMS study, investigating the safety and efficacy of oral once-daily *Gilenya* in children and adolescents (ages 10 to 17) with multiple sclerosis showed that oral fingolimod resulted in an 82% reduction in the number of relapses in the patient population over a period of up to two years, compared to interferon beta-1a intramuscular injections. In December 2017, the FDA granted *Gilenya* Breakthrough Therapy designation for relapsing forms of multiple sclerosis in pediatric patients (ages 10 to 17). *Gilenya* is not currently approved for pediatric use.

INC280 (capmatinib) is a highly selective MET inhibitor. In June 2016, Novartis initiated ongoing Phase II studies to prospectively explore the predictive value of different mechanisms of MET dysregulation (including MET amplification and MET leading to exon 14 deletion mutation) in advanced non-small cell lung cancer. INC280 is licensed by Novartis from Incyte Corporation.

Jakavi (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. *Jakavi* is currently in Phase III development in acute graft versus host disease and chronic graft versus host disease. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization in the indications of oncology and hematology outside the US. In the second quarter of 2016 the license was amended to also include rights to research, develop and commercialize ruxolitinib in graft-versus-host disease outside the US. Ruxolitinib is marketed in the US as Jakafi® by Incyte Corporation.

KAF156 belongs to a novel class of antimalarial compounds called imidazolopiperazines. It has the potential to clear malaria infection, including resistant strains, as well as to block the transmission of the malaria parasite. As demonstrated in a Phase IIa proof-of-concept trial, the compound is fast-acting and potent across multiple stages of the parasite's lifecycle, rapidly clearing both *P. falciparum* and *P. vivax* parasites. In August 2017 Novartis began a Phase IIb study to test multiple dosing combinations and dosing schedules of KAF156 and lumefantrine, including the feasibility of a single dose therapy in adults, adolescents and children.

Kisqali (ribociclib; formerly LEE011) is a selective cyclin-dependent kinase inhibitor that inhibits two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). In March 2017 the FDA approved *Kisqali* in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer. In August 2017 the EC

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approved *Kisqali* in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with HR+/HER2- locally advanced or metastatic breast cancer. Results from the pivotal Phase III MONALEESA 2 study showed *Kisqali* plus letrozole significantly extended progression free survival (PFS) compared to a standard of care, letrozole, as a first line treatment in postmenopausal women with HR+/HER2- advanced breast cancer. *Kisqali* plus letrozole reduced the risk of disease progression or death by 44% over letrozole alone, significantly extending PFS across all patient subgroups. Novartis is continuing to assess *Kisqali* through the MONALEESA clinical trial program, which includes MONALEESA 2, MONALEESA 3 and MONALEESA 7. These trials are evaluating *Kisqali* in multiple endocrine therapy combinations across a broad range of patients, including men and premenopausal women. In December 2017, *Kisqali* was granted Breakthrough Therapy designation by the FDA for initial endocrine-based treatment of pre- or peri-menopausal women with HR+/HER2- advanced or metastatic breast cancer in combination with tamoxifen or an aromatase inhibitor. *Kisqali* was developed by Novartis as part of a drug discovery collaboration with Astex Pharmaceuticals.

LIK066 is an inhibitor of the sodium-glucose co-transporter-1 (SGLT1) and sodium-glucose co-transporter-2 (SGLT2). The dual mechanism (renal and intestinal) acts to improve multiple metabolic end points including glycemic control, weight, blood pressure and lipid biomarkers. We initiated Phase II dose ranging studies for weight loss in the first half of 2017.

LJN452 (tropifexor) is a potent, non-bile acid, Farnesoid X receptor (FXR) agonist, which is being developed for the treatment of nonalcoholic steatohepatitis (NASH). LJN452 has been shown to reduce steatosis, inflammation, and fibrosis in animal models, alongside a favorable safety profile in first in-human studies. This oral treatment is designed to break the cycle of fatty build-up in the liver and harness the body's built-in mechanisms for coping with excess bile acid. Recruitment is underway for the first LJN452 clinical study in NASH patients.

OMB157 (ofatumumab) is a fully human monoclonal antibody administered by subcutaneous injection in development for multiple sclerosis (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 2014 and showed significant reduction in the number of new brain lesions in the first 24 weeks after ofatumumab administration. Novartis initiated a Phase III program for OMB157 in relapsing MS in August 2016. The program is on track, and we expect to complete the Phase III program in MS in 2019. Ofatumumab is marketed by Novartis for oncology indications as an intravenous infusion under the brand name *Arzerra*.

PDR001 (spartalizumab) is a PD-1 antagonist that may restore the ability of immune cells to induce cell death and fight cancer. PDR001 is being evaluated in a Phase III trial in combination with *Tafinlar* + *Mekinist* for metastatic BRAF V600+ melanoma, in a Phase II trial for neuroendocrine tumors and in Phase I trials in other tumor types.

QAW039 (fevipiprant) is being investigated in the reduction of asthma attacks in patients with severe asthma and in the improvement of lung function in patients with moderate asthma. This compound is designed to block the activity of the DP2 receptor, an upstream driver of allergen- and non-allergen dependent inflammation in asthma, resulting in reduction in IL-4, IL-5, and IL-13, inhibition of eosinophil migration, and inhibition of smooth muscle cells growth in the airway. Phase II clinical data shows a positive effect on symptoms (asthma control questionnaire) and lung function, and reduction in sputum eosinophils.

QMF149 (indacaterol acetate/mometasone furoate) is a once daily fixed-dose combination being investigated in asthmatic patients who are uncontrolled on an inhaled corticosteroid. QMF149 combines indacaterol acetate (an inhaled long-acting beta$_2$-adrenergic agonist with 24 hour duration of action) and mometasone furoate (an inhaled corticosteroid with 24 hour duration of action) delivered via the *Breezhaler* device, a single dose dry powder inhaler. QMF149 is currently being evaluated in two Phase III clinical trials to support registration outside the US.

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QVM149 (indacaterol acetate, glycopyrronium bromide, mometasone furoate) is a fixed-dose combination of indacaterol acetate (an inhaled long-acting beta$_2$-adrenergic agonist with 24 hour duration of action), glycopyrronium bromide (an inhaled long-acting muscarinic antagonist with 24 hour duration of action), and mometasone furoate (an inhaled corticosteroid with 24 hour duration of action) in development for once-daily maintenance treatment of poorly controlled asthmatic patients to be delivered via the *Breezhaler* device, a single dose dry powder inhaler. All three mono-components have previously been developed as individual drugs for either chronic obstructive pulmonary disease or asthma. QVM149 is currently in Phase III clinical trials to support registration outside the US.

RLX030 (serelaxin) is a novel recombinant form of the human hormone relaxin 2, and is believed to act through multiple mechanisms to reduce stress on the heart, kidneys and other organs. In 2017 Novartis announced the global Phase III RELAX-AHF-2 study investigating the efficacy, safety and tolerability of RLX030 in patients with acute heart failure (AHF) did not meet its primary endpoints of reduction in cardiovascular death through day 180 or reduced worsening heart failure through day five when added to standard therapy in patients with AHF.

RTH258 (brolucizumab) is a single-chain antibody fragment that acts as an anti-vascular endothelial growth factor (anti-VEGF) agent. RTH258 is currently in development for neovascular age related macular degeneration (nAMD) and diabetic macular edema. RTH258 met its primary endpoint of non-inferiority to aflibercept in mean change in best-corrected visual acuity in two Phase III clinical trials, HAWK and HARRIER. Additionally, superiority was shown in three secondary endpoints that are considered key markers of nAMD disease, central subfield retinal thickness, retinal fluid and disease activity. Additionally, a majority of patients were on a 12-week treatment schedule immediately following the loading phase, also assessed by secondary endpoints in the HAWK and HARRIER trials. Beginning in 2018, we expect to make regulatory filings for nAMD in the US, EU and Japan. RTH258 is also currently in development for diabetic macular edema, with Phase III trials in this indication scheduled to start in 2018.

SEG101 (crizanlizumab) is a humanized anti-P-selectin monoclonal antibody that is being investigated in the reduction of vaso-occlusive pain crises in patients with sickle cell disease (SCD). SCD is a hereditary blood disorder characterized by sickle-shaped red blood cells. Novartis acquired SEG101 in 2016 by exercising its right to acquire Reprixys Pharmaceuticals Corporation following receipt of results of the Phase II SUSTAIN study. Results from the Phase II SUSTAIN study demonstrated that SEG101 reduced the median annual rate of sickle cell-related pain crises compared to placebo in patients with or without hydroxyurea therapy.

Signifor LAR (pasireotide) is a somatostatin analogue approved in the EU in September 2017 as a long-acting release formulation for patients with Cushing's disease. An application for this indication has also been accepted by the FDA.

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 MAP kinase pathway, resulting in dual blockade of this pathway, which is the main escape mechanism for resistance. *Tafinlar + Mekinist* (dabrafenib + trametinib) is the first combination of BRAF and MEK inhibitors to report three years of follow-up survival data in two Phase III studies in BRAF V600+ unresectable or metastatic patients. A Phase III study is also underway for BRAF V600 mutation positive melanoma patients in the adjuvant setting. Phase II studies are also underway to evaluate the efficacy and safety of *Tafinlar + Mekinist* in patients with BRAF V600 mutation positive non-small cell lung cancer. Data presented at a major European conference in the third quarter showed reduced risk of disease recurrence by 53% in patients with resected BRAF V600 mutation-positive melanoma and meaningful improvements in secondary endpoints, including overall survival, distant metastasis-free survival and freedom from relapse. In October 2017, the FDA granted Breakthrough Therapy designation for *Tafinlar + Mekinist* for the adjuvant

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treatment of patients with stage III melanoma with a BRAF V600 mutation following complete resection. In December 2017, the FDA granted Priority Review to *Tafinlar + Mekinist* for adjuvant treatment of this patient population. *Tafinlar + Mekinist* is being evaluated in a Phase III trial in combination with PDR001 for metastatic BRAF V600+ melanoma, in a Phase II trial for neuroendocrine tumors and in Phase I trials in other tumor types.

UNR844 is a potential first-in-class topical treatment in development for presbyopia. UNR844 is believed to work through reduction of disulfide bonds, softening the crystalline lens. Presbyopia is a common age-related loss of near distance vision characterized by a progressive inability to focus on objects nearby, making everyday activities, such as reading, challenging. In a Phase I/II masked, placebo-controlled proof of concept study, 50 patients were treated daily for 90 days with topical UNR844 and 25 patients with placebo. UNR844 showed a statistically significant difference to placebo in distant corrected near vision at all time points measured (from day 8). At day 90, 82% of participants treated with UNR844 had 20/40 near vision (or 0.30 LogMAR) versus 48% in the placebo group. Near vision of 20/40 allows for the majority of near vision tasks in most people. UNR844 was acquired by Novartis through the acquisition of Encore Vision, Inc., in January 2017.

VAY736 is a highly specific and potent monoclonal antibody against the B-cell activating factor receptor (BAFF-R) with enhanced antibody-dependent cell-mediated cytotoxicity against BAFF-R positive B cells. VAY736 is in Phase II development for the treatment of primary Sjogren's syndrome, a systemic autoimmune disorder characterized by progressive lymphocytic destruction of exocrine glands and other organs resulting not only in eye and mouth dryness, but frequently complicated by severe fatigue and extraglandular organ involvement. VAY736 is also being tested for patients with autoimmune hepatitis, a chronic autoimmune disorder, characterized by hepatocyte injury and destruction of the liver architecture leading to fibrosis/cirrhosis, and ultimately to end stage liver disease requiring liver transplantation.

VAY785 (emricasan) is an investigational, first-in-class, oral, pan-caspase inhibitor being investigated for the treatment of chronic liver diseases including nonalcoholic steatohepatitis (NASH) with advanced fibrosis (scarring) and cirrhosis. In multiple Phase II clinical trials, VAY785 has demonstrated significant, rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death, which play a role in the severity and progression of liver disease. VAY785 is being developed in collaboration with Conatus Pharmaceuticals Inc. As part of this collaboration, Conatus is conducting several Phase IIb clinical trials with VAY785, including the ENCORE-PH trial in primarily compensated NASH cirrhosis, the POLT-HCV-SVR trial in post-transplant hepatitis C virus fibrosis and cirrhosis, and the ENCORE-NF in NASH fibrosis. Top-line results of these trials are expected to be available starting in 2018 and continuing thereafter. In May 2017, Conatus also initiated the Phase IIb ENCORE-LF trial in patients with decompensated liver cirrhosis caused by NASH, with results expected in the second half of 2019.

ZPL389 is a once-daily oral H_4 receptor antagonist in development for atopic dermatitis, commonly known as eczema. ZPL389 is a potential first-in-class oral treatment for moderate-to-severe eczema. In a proof of concept study, ZPL389 showed a clinically and statistically significant reduction of eczema. After eight weeks of treatment, the compound reduced the Eczema Area and Severity Index (EASI) score by 50% in a study of 98 patients. In clinical studies conducted to date, ZPL389 has a favorable safety profile. ZPL389 was acquired by Novartis through the acquisition of Ziarco Group Limited in January 2017.

Zykadia (ceritinib) is a potent and highly selective oral anaplastic lymphoma kinase (ALK) inhibitor that is in development for ALK positive (ALK+) cancers. In May 2017, the FDA approved the expanded use of *Zykadia* to include the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors are ALK+, as detected by an FDA-approved test. In June 2017 the European Commission approved expanding the use of *Zykadia* to the first-line treatment of patients with advanced non-small cell lung cancer whose tumors are ALK+.

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Projects Added to and Subtracted from the Development Table Since 2016

Project/Product	Potential indication/ Disease area	Change	Reason
ABL001	Chronic myeloid leukemia, 1st line	Added	Entered confirmatory development
ACZ885	2nd line non-small cell lung cancer	Added	Entered confirmatory development
	1st line non-small cell lung cancer	Added	Entered confirmatory development
	Adjuvant non-small cell lung cancer	Added	Entered confirmatory development
Arzerra	Refractory non-Hodgkin's lymphoma	Now disclosed as refractory indolent non-Hodgkin's lymphoma; and Route of administration corrected	
CFZ533	Solid organ transplantation	Added	Entered confirmatory development
CJM112	Immune disorders	Removed	Development discontinued
Cosentyx	Psoriatic arthritis head to head study vs. adalimumab	Now disclosed as psoriatic arthritis head to head study vs. Humira® (adalimumab)	
	Ankylosing spondylitis head to head study vs. adalimumab	Now disclosed as ankylosing spondylitis head to head study vs. proposed Sandoz biosimilar adalimumab	
CTL019 (approved in the US as *Kymriah*)	Pediatric acute lymphoblastic leukemia	Now disclosed as pediatric/young adult acute lymphoblastic leukemia	
	Diffuse large B-cell lymphoma	Now disclosed as 3rd line diffuse large B-cell lymphoma	

Relapsed/refractory follicular lymphoma	Added	Entered confirmatory development

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Project/Product	Potential indication/ Disease area	Change	Reason
	Chronic lymphocytic leukemia	Added	Entered confirmatory development
	Relapsed/refractory diffuse large B-cell lymphoma in 1st relapse	Added	Entered confirmatory development
	Relapsed/refractory diffuse large B-cell lymphoma (+pembrolizumab)	Added	Entered confirmatory development
ECF843	Dry eye	Added	Entered confirmatory development
EGF816	Non-small cell lung cancer	Added	Entered confirmatory development
EMA401	Neuropathic pain	Now disclosed as peripheral neuropathic pain	
HDM201	Acute myeloid lymphoma	Added	Entered confirmatory development
Ilaris	Periodic fever syndromes	Commercialized	
Jakavi	Early myelofibrosis	Removed	Development discontinued
	Graft-versus-host disease	Now disclosed as acute graft-versus-host disease	
	Chronic graft-versus-host disease	Added	Entered confirmatory development
Kisqali (LEE011)	Hormone receptor-positive, HER2-negative advanced breast cancer (postmenopausal women), 1st line (+ letrozole)	Commercialized as *Kisqali*	
LHW090	Resistant hypertension	Added	Entered confirmatory development
LMI070	Spinal muscular atrophy	Added	Entered confirmatory development

LOU064	Chronic spontaneous urticaria	Added	Entered confirmatory development
MAA868	Stroke prevention in atrial fibrillation	Added	Entered confirmatory development

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Project/Product	Potential indication/ Disease area	Change	Reason
MTV273	Multiple myeloma	Added	Entered confirmatory development
PDR001	Endocrine neoplasm	Added	Entered confirmatory development
	Malignant melanoma (w/ *Tafinlar* + *Mekinist*)	Added	Entered confirmatory development
	Neuroendocrine tumors	Added	Entered confirmatory development
PIM447	Hematologic tumors	Removed	In exploratory development
PKC412 *(Rydapt)*	Acute myeloid leukemia	Commercialized as *Rydapt*	
	Advanced systemic mastocytosis	Commercialized as *Rydapt*	
QAW039	Atopic dermatitis	Removed	Development discontinued
QBW251	Chronic obstructive pulmonary disease	Added	Entered confirmatory development
	Cystic fibrosis	Removed	In exploratory development
RLX030	Acute heart failure	Removed	Development discontinued
Tafinlar + *Mekinist*	BRAF V600+ non-small cell lung cancer	Commercialized	
	BRAF V600+ colorectal cancer	Removed	Development discontinued
Tasigna	Chronic myeloid leukemia treatment-free remission	Commercialized	
VAY736	Autoimmune hepatitis	Added	Entered confirmatory development
VAY785	Nonalcoholic steatohepatitis	Added	Entered confirmatory development
Xolair	Nasal polyps	Added	Entered confirmatory

		development
Zykadia	ALK + advanced non-small cell lung cancer (1st line, treatment naïve)	Commercialized

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Project/Product	Potential indication/ Disease area	Change	Reason
	ALK + advanced non-small cell lung cancer (brain metastases)	Removed	Development discontinued

Principal Markets

The Innovative Medicines Division sells products in approximately 155 countries worldwide. Net sales are generally concentrated in the US, Europe and Japan. The following table sets forth the aggregate 2017 net sales of the Innovative Medicines Division by region:

Innovative Medicines	2017 Net sales to third parties	
	$ millions	%
Europe	11,289	34
United States	11,116	34
Asia, Africa, Australasia	7,875	24
Canada and Latin America	2,745	8
Total	**33,025**	**100**
Of which in Established Markets*	24,633	75
Of which in Emerging Growth Markets*	8,392	25

* 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 Innovative Medicines 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 and quality standards. 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 our products at facilities worldwide. See also " Item 4.D Property, Plants and Equipment." Active pharmaceutical ingredients are manufactured in our own facilities or purchased from third-party suppliers. We maintain state-of-the-art processes with quality as a primary goal within our own production network. Those processes include fermentation, chemical syntheses and precipitation processes, such as sterile processing. Many biologic medicines 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, and review and adapt our manufacturing network to meet the needs of our Innovative Medicines Division.

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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.

Because the manufacture of our products is complex and heavily regulated by governmental health authorities, 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 experienced supply interruptions for our products 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. 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 always be able to successfully manage such issues when they arise.

Marketing and Sales

The Innovative Medicines Division serves customers with 3,360 field force representatives in the US, and an additional 22,161 in the rest of the world, as of December 31, 2017, 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.

The marketplace for healthcare is also evolving with patients 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.

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.

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

As a result of continuing changes in healthcare economics and an aging population, the US Centers for Medicare & Medicaid Services (CMS) is the largest single payor for healthcare services in the US. In addition, both commercial and government sponsored managed care organizations continue to be among the largest groups of payors for healthcare services in the US. In other countries, 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.

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Recent trends have been toward continued consolidation among distributors and retailers of Innovative Medicines Division products, both in the US and internationally. This has increased our customers' purchasing leverage and resulted in increased pricing pressure on our products. Moreover, we are exposed to increased concentration of credit risk as a result of the consolidation among our customers.

Competition

The global pharmaceutical market is highly competitive, and we compete against other major international corporations which have substantial financial and other resources, as well as against smaller companies which operate regionally or nationally. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

In addition, as is the case with other pharmaceutical companies selling patented pharmaceuticals, Novartis faces ever-increasing challenges from companies selling products which compete with our products, including competing patented products and generic forms of our products following the expiry of intellectual property protection. Generic companies may also gain entry to the market through successfully challenging our intellectual property rights, but we vigorously use legally permissible measures to defend those rights. See also " Intellectual Property" below. We also may 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

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.

We are a leader in the pharmaceuticals industry in terms of research and development, including the level of our investment. For information about research and development expenditures by our Innovative Medicines Division over the last three years, please see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Results of Operations 2017 Compared to 2016 Innovative Medicines Research and development of Innovative Medicines Division," and "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Results of Operations 2016 Compared to 2015 Innovative Medicines Research and development of Innovative Medicines Division."

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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 2002. 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 alliances with clinical colleagues, and the establishment of appropriate external complementary alliances.

At NIBR sites in Basel, Switzerland, Cambridge, Massachusetts, three other US locations, and Shanghai, China, approximately 6,000 full-time equivalent scientists, physicians and business professionals contribute to research into disease areas such as cardiovascular and metabolic diseases, neuroscience, oncology, muscle disorders, ophthalmology, autoimmune diseases, and respiratory diseases. In addition, the Novartis Institute for Tropical Diseases (NITD), the Friedrich Miescher Institute, and the Genomics Institute of the Novartis Research Foundation focus on basic genetic and genomic research. NITD is currently focused on parasitic pathogens, including malaria and cryptosporidiosis.

All drug candidates are taken to the clinic via "proof-of-concept" trials to enable an early assessment of the safety and efficacy of the drug while collecting basic information on pharmacokinetics and tolerability, and adhering to the guidance for early clinical testing set forth by health authorities. Following proof-of-concept, our Global Drug Development unit conducts confirmatory trials on the drug candidates.

In October 2016, we announced a new strategic plan for research that includes the creation of a unified early discovery research group based in Basel, Switzerland and Cambridge, Massachusetts, the creation of two centers of excellence for bio-therapeutic research in Basel, Switzerland and Cambridge, Massachusetts, the creation of an enterprise wide pharmacokinetics sciences group and growth of our respiratory diseases research group. As part of this plan, the Novartis Institute for Tropical Diseases (NITD) moved its research programs and operations from Singapore to Emeryville, California, where, as of June 2017, it is co-located with our infectious diseases research team. The creation of the two centers of excellence in bio-therapeutics resulted in the closure of a biologics group in Shanghai, China and the closure of ESBATech, a biologics group in Schlieren, Switzerland in 2017. In 2017 we also completed the exit of all internal non-human primate research resulting in the closure of operations focused on non-human primate research in Fort Worth, Texas.

Development program

Our Global Drug Development (GDD) organization oversees drug development activities for our Innovative Medicines Division. GDD works collaboratively with NIBR to execute our overall pipeline strategy and takes an enterprise approach to pipeline and portfolio management. The GDD organization includes centralized global functions such as Regulatory Affairs and Global Development Operations, and Global Development units aligned with our business franchises. GDD was created to improve resource allocation, technology implementation and process standardization to further increase innovation. GDD includes approximately 10,000 full-time equivalent associates worldwide.

Under our Global Drug Development unit, the focus of our development program is to determine the safety and efficacy of a potential new medicine in humans.

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

Phase I: These are the first clinical trials of a new compound, generally performed in a small number of healthy human volunteers, to assess the drug's safety profile, including the safe dosage range. These trials also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action.

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Phase II: Clinical studies 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 in 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.

In each of these phases, physicians monitor volunteer patients closely to assess the potential new drug's safety and efficacy.

Though we use this traditional model as a platform, we have tailored the development process to be simpler, more flexible and efficient. We view the development process as generally consisting of Exploratory Development where "proof of concept" is established, and Confirmatory Development where this concept is confirmed in large numbers of patients. 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 and are conducted by NIBR. Once a positive proof of concept has been established, the drug moves to the Confirmatory Development stage and becomes the responsibility of GDD. 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 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. For more information, see " Regulation."

At each phase 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 and oversees our drug development budget. 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 our Global Head of Drug Development and Chief Medical Officer and has representatives from Novartis senior management with expertise spanning multiple fields, among its core members and extended membership.

Alliances and acquisitions

Our Innovative Medicines Division enters into business development agreements with other pharmaceutical and biotechnology companies and with academic and other 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.

On January 19, 2018, we successfully completed our previously-announced tender offer for all of the then outstanding ordinary shares, including ordinary shares represented by American Depositary Shares (ADSs), of Advanced Accelerator Applications S.A. (AAA). As of the expiration of the offer on January 19, 2018, approximately 97% of the then outstanding fully diluted ordinary shares, including

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ordinary shares represented by ADSs, were validly tendered. In addition, on January 22, 2018, we commenced a subsequent offering period which will expire on January 31, 2018, unless extended. AAA is a NASDAQ-listed radiopharmaceutical company headquartered in Saint-Genis-Pouilly, France, that develops, produces and commercializes molecular nuclear medicines including *Lutathera* (lutetium (^{177}Lu) oxodotreotide), a first-in-class radioligand therapy product for neuroendocrine tumors and a portfolio of diagnostic products. For additional information, see "Note 2. Significant transactions Significant transaction entered into in 2017 and closed in January 2018" on page 199 of the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

In November 2017, we announced an expanded collaboration with Amgen Inc., and the Banner Alzheimer's Institute to collaborate on a new Generation Study 2 to assess whether investigational BACE1 inhibitor CNP520 can prevent or delay the symptoms of Alzheimer's disease in a high-risk population.

In September 2017, we announced a collaboration agreement with the University of California, Berkeley, (UCB) in the field of covalent chemoproteomics to establish the Novartis-Berkeley Center for Proteomics and Chemistry Technologies, based at Berkeley. The collaboration will focus on discovery of drug targets on proteins inaccessible to conventional therapeutic molecules.

In June 2017, we announced a clinical research collaboration in which Bristol-Myers Squibb is to investigate the safety, tolerability, and efficacy of *Mekinist* (trametinib) in combination with Opdivo® (nivolumab) and Opdivo® + Yervoy® (ipilimumab) regimen as a potential treatment option for metastatic colorectal cancer in patients with microsatellite stable tumors where the tumors are proficient in mismatch repair (MSS mCRC pMMR).

In April 2017, Novartis announced an expanded collaboration agreement with Amgen to co-commercialize AMG 334 (erenumab) in the US, currently being investigated for the prevention of migraine. Novartis retains exclusive rights to commercialize AMG 334 in the rest of the world and gains commercialization rights in Canada. This agreement builds on the previously-announced 2015 global collaboration between Novartis and Amgen.

In January 2017, we entered into a collaboration and option agreement with Ionis Pharmaceuticals, Inc. (Ionis), and its affiliate Akcea Therapeutics, Inc. (Akcea), to license two investigational treatments with the potential to significantly reduce cardiovascular risk in patients suffering from high levels of lipoproteins known as Lp(a) and ApoCIII. The two investigational antisense therapies developed by Ionis called AKCEA-APO(a)-L_{Rx} and AKCEA-APOCIII-L_{Rx} have the potential to lower both lipoproteins up to 90% and significantly reduce cardiovascular risk in high-risk patient populations. In addition, Novartis entered into a stock purchase agreement with Ionis and Akcea. This transaction was completed on February 14, 2017.

In December 2016, we entered into a definitive agreement for the acquisition of Encore Vision, Inc., a privately-held company focused on the development of UNR844 (formerly EV06), an investigational, first-in-class potentially disease modifying topical treatment for presbyopia. This acquisition was completed on January 20, 2017.

In December 2016, we signed an exclusive option, collaboration and license agreement with Conatus Pharmaceuticals Inc., for the global rights to VAY785 (emricasan), an investigational, first-in-class, oral, pan-caspase inhibitor for the treatment of non-alcoholic steatohepatitis with advanced fibrosis and cirrhosis of the liver. Novartis exercised the option on May 4, 2017. Novartis obtained an exclusive, worldwide license to develop and commercialize products containing emricasan on July 5, 2017.

In December 2016, we entered into a definitive agreement for the acquisition of Ziarco Group Limited, a privately held company focused on the development of novel treatments in dermatology including ZPL389, a once-daily oral H_4 receptor antagonist in development for atopic dermatitis. This acquisition was completed on January 20, 2017.

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In November 2016, we acquired Reprixys Pharmaceuticals Corporation and SEG101 (crizanlizumab), an anti-P-selectin antibody being investigated in the reduction of vaso-occlusive pain crises in patients with sickle cell disease.

In June 2016, we announced a collaboration and licensing agreement with Xencor for the development of bispecific antibodies for treating cancer. We are to collaborate with Xencor to co-develop their two bispecific T cell engaging antibodies targeting CD3xCD123 and CD3xCD20 for the treatment of acute myeloid leukemia and B-cell malignancies. As part of the agreement, Novartis also received the right to develop four additional bispecific antibodies and to use other Xencor proprietary antibody engineering technology for up to ten additional biotherapeutic programs across the Novartis research and development portfolio.

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. These programs target regulatory T cell populations, inhibitory cytokines, and immunosuppressive metabolites in the tumor microenvironment.

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 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.

As part of our previously-announced exclusive global research and development collaboration with the University of Pennsylvania (Penn) to develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies for the treatment of cancer, in February 2016 Penn opened the Center for Advanced Cellular Therapeutics (CACT) at the Perelman School of Medicine campus in Philadelphia, Pennsylvania. The CACT is 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.

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. 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

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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, efforts have been made among the US, the EU and Japan to harmonize registration requirements in order to achieve shorter development and registration times for medical products. However, the requirement in many countries to negotiate selling prices or reimbursement levels with government regulators 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 Innovative Medicines 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, including experts 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

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post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the product under specified conditions.

Throughout the life cycle of a product, the FDA requires compliance with standards relating to good laboratory, clinical and manufacturing practices. The FDA also requires compliance with rules pertaining to the manner in which we may promote our products.

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 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. The holder of the Marketing Authorization must actively apply for its renewal after this first five year period. As part of the renewal procedure, the competent authority will perform a full benefit-risk review of the product. Should

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the authority conclude that the benefit-risk balance is no longer positive, the Marketing Authorization can be suspended or revoked. Once renewed the Marketing Authorization is valid for an unlimited period. If the holder does not apply for renewal, the Marketing Authorization automatically lapses. 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 specified conditions. The MHLW also requires the drug's sponsor to submit periodic safety update reports. Within three months from the specified re-examination period, which is designated at the time of the approval of the application for the new product, the company must submit a re-examination application to enable the drug's safety and efficacy to be reassessed against approved labeling by the PMDA.

Price Controls

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

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Direct governmental 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 prospective prescription drug discounts or rebates, which could limit net prices for our products. The Medicare Trustees' Report from June 2017 predicted that the projected 5-year average growth in per capita Medicare program spending is not likely to exceed a specified target level until 2022. 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 the following year based on a savings target set by the Chief Actuary, to be implemented in the second following year. In October 2017, a bill to repeal the IPAB was passed by the House of Representatives and currently awaits consideration by the Senate. There is also a strong possibility that government officials will continue to search for additional ways to reduce or control prices, including state legislation mandating drug price controls, which could include limits on annual price increases or maximum price levels. In 2017, several states passed legislation impacting pricing or requiring price transparency reporting, including California, Louisiana, Nevada and Maryland. The California law will require 60 day advance notification of price increases for products exceeding a specific threshold over the past two years, as well as additional quarterly reporting requirements.

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 patients. 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, access to innovative medicines is limited based on strict cost-benefit assessments. In addition, prices for marketed products are referenced within Member States and across Member State borders, further impacting individual EU Member State pricing. As an additional control for healthcare budgets, some EU countries have passed legislation to impose further mandatory rebates for pharmaceutical products and/or financial claw-backs on the pharmaceutical industry. The calculation of these rebates and claw-backs can be difficult to predict.

Japan. In 2016, 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 2016. In addition, the MHLW implemented extraordinary price cuts in 2016 for certain products the sales of which have increased more than 100 billion Japanese Yen (one and one half times more than official forecasts). The Japanese government is continuing deliberations of 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. In December 2016, the Japanese government also announced basic reform principles for fundamental reforms of the drug pricing system to be implemented in 2018. Based on these principles, which include an increase in the frequency of price cuts from every other year to annually, a revision to the premium system which basically maintains the price of patented drugs for unmet medical needs, and the introduction of a cost effectiveness

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assessment, the government is deliberating and undertaking fundamental reforms of the drug pricing system in 2017 which will be introduced at the next regular price revision scheduled for April 2018.

Rest of World. Many other countries around the world are also taking steps to control prescription drug prices. For example, in 2017, China, one of our most important emerging growth markets, organized national price negotiations for certain products directly linked to national drug reimbursement, which will apply nationwide both in public and military hospitals, with drug price reductions of more than 60% in some cases. Drug prices in China may further decline due to a stated national policy of reducing healthcare costs, including continued strategic initiatives specifically designed to reduce drug prices. Canada has proposed amendments to its Patented Medicines Regulations in 2017 that could reduce prices for specialty medicines, such as biologics and medicines for rare diseases, by as much as 30% to 40%. In addition, in 2016, the Colombian government took steps to unilaterally reduce the price of *Glivec* by up to 43% through a local procedural mechanism called a Declaration of Public Interest. While the government's use of this exceptional mechanism as a tool to control the price of a prescription drug and to generally manage its healthcare budget is unprecedented, we continue to contest its appropriateness with respect to *Glivec* in Colombia, as its use could become more widespread if upheld in this case, potentially leading to a more systemic impact on drug pricing.

Regulations favoring generics and biosimilars

In response to rising healthcare costs, most governments and private medical care providers 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 crafting 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. Given the increased focus on pharmaceutical prices in the US, certain members of the US Congress and select state legislators continue to explore legislation to allow the safe importation of pharmaceutical products into the US from select countries, including Canada.

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.

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Intellectual Property

We attach great importance to intellectual property including patents, trademarks, copyrights, know-how and research data in order to protect our investment in research and development, manufacturing and marketing. In general, we seek intellectual property protection under applicable laws for significant product developments in major markets. Among other things, patents may cover the products themselves, including the product's active ingredient or ingredients and its formulation. Patents may cover processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the product. 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 can improve patient outcomes when administered certain drugs, as well as assays, research tools and other techniques used to identify new drugs. The protection offered by such patents extends for varying periods depending on the grant and duration of patents in the various countries or region. The protection afforded, which may vary from country to country, depends upon the type of patent and its scope of coverage.

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

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 delays in patent issuance based upon certain delays in prosecution by the United States Patent and Trademark Office (USPTO). 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.

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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.

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 European Patent Office (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. The term of a patent granted by the EPO or a European country office is generally 20 years from the filing date of the patent application on which the patent is based, subject to potential patent term extensions and adjustments. Pharmaceutical patents can 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 Pediatric Extension of 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.

In practice, as in the US, it is not uncommon for patent term extensions to not fully compensate the owner of a patent for the time it took to develop the product and receive marketing authorization by the European health authorities. Accordingly, it is not uncommon that a pharmaceutical product, at the date of approval, will have a patent lifetime of 10 to 15 years, including 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

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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.

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. Under certain circumstances, this exclusivity can be extended with a 2-year Pediatric Extension.

Japan

Patents

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, subject to potential patent term extensions and adjustments. 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. As in the US and EU, patent term extensions in Japan may not fully compensate for the time necessary to develop a product and obtain a marketing authorization. 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, including available extensions.

Data and Market Exclusivity

Japan also has a regulatory data protection system called a "re-examination period" of 8 years for new chemical entities and 4-6 years for new indications and formulations and a 10 year orphan drug exclusivity system.

Third Party Patents and Challenges to Intellectual Property

Third parties can challenge our patents, patent term extensions and marketing exclusivities, including pediatric extensions and orphan drug exclusivity, through various proceedings. For example, patents in the US can be challenged in the 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 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. The outcomes of such challenges can be difficult to predict.

In addition to directly challenging our intellectual property rights, in some circumstances a competitor may be able to market a generic version of one of our products 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 a risk that some countries may seek to impose limitations on the availability of intellectual property right protections for pharmaceutical products, or on the extent to which such protections may be enforced. For example, a review of several intellectual property rights is currently ongoing in the EU (orphan drug

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exclusivity, pediatric extensions, SPCs and regulatory data protection), which could lead to legislative changes in the scope and/or term of protection under those rights. Also, even though we may own, co-own or in-license patents protecting our products, and conduct pre-launch freedom-to-operate analyses, a third party may nevertheless claim that one of our products infringes a third party patent for which we do not have a license.

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 or from third party patents in the future.

Intellectual Property Protection for Certain Key Marketed Products and Compounds in Development

We present below certain additional details regarding intellectual property protection for certain Innovative Medicines Division products and compounds in development. For each product and compound in development below, we identify 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 the product or to the method of its use as it is currently approved and marketed or, in the case of a compound in development, as it is currently filed with the FDA and/or the EMA for approval. Novartis may own or control additional patents relating to compound forms, methods of use, formulations, processes, synthesis, purification and detection.

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 the products and compounds in development below 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 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, identification of a patent, patent term extension, marketing exclusivity or data protection means grant, authorization and maintenance in at least one country and possibly pending or found invalid in others. Marketing exclusivities and patent term extensions include orphan drug exclusivity (ODE), pediatric exclusivity (PE), patent term extension (PTE) and SPC.

For each product below, we indicate whether there is current generic competition, which in the case of products containing biologics refers to biosimilar competition, for one or more product versions in one or more approved indications in each of the major markets for which intellectual property is disclosed. We identify ongoing challenges to the disclosed intellectual property that have not been finally resolved, including IPRs if instituted by the USPTO. Challenges identified as being in administrative entities, such as national patent offices, include judicial appeals from decisions of those entities. Resolution of challenges to the disclosed intellectual property, which in the EU may involve intellectual property of one or more EU countries, may include settlement agreements under which Novartis permits or does not permit future launch of generic versions of our products before expiration of that intellectual property. We identify certain material terms of such settlement agreements where they could have a material adverse effect on our business. In other cases, such settlement agreements may contain confidentiality obligations restricting what may be disclosed.

For additional information regarding commercial arrangements with respect to these products, see " Key Marketed Products."

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Novartis Oncology Business Unit

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 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 generic competition in the US, EU and Japan. In the US and EU Novartis has resolved patent litigation with certain generic manufacturers. Novartis is taking steps in some EU countries to enforce the polymorphic compound form patent, the tablet formulation patent and the GIST method of use patent. The EU GIST method of use patent and polymorphic compound patent are being challenged in the patent offices and courts of several EU countries. The EU tablet formulation patent is being challenged in the EPO and in the patent office of one EU country.

Tasigna. US: Patent on compound (2023), pending PE (2024); patents on salt forms (2026, 2027, 2028), pending PE (2027, 2028, 2029); patent on polymorph compound form (2026), pending PE (2027); patents on capsule form (2026, 2027), pending PE (2027, 2028) and patent on method of treatment (2032), pending PE (2033). EU: Patent on compound (2023); patent on polymorph compound form (2026); patent on capsule form (2027); method of treatment (2030); ODE (2017), PE (2019). Japan: Patent on compound (2023), PTE (2024); patent on salt form (2026); patent on polymorph compound form (2026); patent on capsule form (2027).

There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging the salt form patents, the polymorph patent, the capsule form patent and the method of treatment patent. The EU method of treatment patent, the capsule form patent, and the polymorph compound patent are being opposed in the EPO.

Sandostatin SC and *Sandostatin LAR.*

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: There is no patent protection in the US, EU or Japan. There is currently no generic competition in the US, EU or Japan.

Afinitor/Votubia and *Afinitor Disperz/Votubia* dispersible tablets. US: Patent on compound (2014), PTE (2019), PE (2020); patent on dispersible tablet formulation (2022), PE (2023); two patents on antioxidant (2019), PE on one patent on antioxidant (2020); patent on tuberous sclerosis complex (TSC)/subependymal giant cell astrocytoma (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); RDP for NET of gastrointestinal or lung origin (2019), PE (2019); ODE for TSC/SEGA use (2017), PE (2018); ODE for pancreatic neuroendocrine tumors use (2018), PE (2018); ODE for TSC/renal angiomyolipoma (2019), PE (2019). EU: Patent on compound (2013), SPC (2018), PE (2019); patent on dispersible tablet formulation (2022); patent on antioxidant (2019); patent on breast cancer use (2022); patent on renal cell carcinoma use (2022); patent on TSC/SEGA use (2022); ODE (*Votubia*) (2021). Japan: Patent on compound (2013), PTEs for certain indications/dosages (2018); 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); patent on gastrointestinal and lung neuroendocrine tumor use (2026), PTE (2027); patent on TSC/SEGA and TSC/AML use (2027); ODE (tuberous sclerosis) (2022); ODE (dispersible tablet) (2022). There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging the compound patent and the patents on breast

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cancer use, pancreatic neuroendocrine tumor use, renal cell carcinoma use and RSC/SEGA use. The US compound, renal cell carcinoma use and pancreatic neuroendocrine tumor use patents are being challenged in IPR proceedings in the USPTO. In the US, Novartis has resolved patent litigation with a generic manufacturer. The EU breast cancer use patent, the EU TSC/SEGA use patent and the EU renal cell carcinoma use patent are being opposed in the EPO. The Japanese breast cancer use patent is being challenged in the Japanese Patent Office.

Exjade and *Jadenu.*

Exjade: US: Patent on compound (2017), PTE (2019), ODE for non-transfusion iron overload (2020). EU: Patent on compound (2017), SPC (2021); patent on dispersible tablet formulation (2023). Japan: Patent on compound (2017), PTE (2021); patent on dispersible tablet formulation (2023). 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 (marketed as *Exjade* FCT in EU and Japan): The compound patents for *Exjade* also protect *Jadenu* (US), and *Exjade* FCT (EU/Japan). US: Formulation patent for film coated tablets (2034), ODE for non-transfusion iron overload (2020). EU: Formulation patent for film coated tablets (2034). There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging the formulation patent.

Tafinlar and *Mekinist.*

Tafinlar: US: Two patents on compound (2030; 2030); patent on method of use (2029); RDP (2018); ODE (2020). EU: Patent on compound (2029); RDP (2023). Japan: Patent on compound (2031). There is currently no generic competition in the US, EU or Japan. The EU compound patent is being opposed in the EPO.

Mekinist: US: Patent on compound (2025), pending PTE (2027); patent on method of use (2025); three patents on formulation (2032; 2032; 2032); RDP (2018); ODE (2020). EU: Patent on compound (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 *Tafinlar* or *Tafinlar* with *Mekinist*: US: Patent on combination (2030) ; patent on method of use of combination (2030); RDP on melanoma indication (2018), RDP on non-small cell lung cancer indication (2020); ODE on melanoma with certain mutations (2021), ODE on non-small cell lung cancer (2024). EU: RDP (2025). Japan: Patent on method of use of combination (2030). There is currently no generic competition in the US, EU or Japan.

Promacta/Revolade. US: Patent on compound (2021), PTE (2022), PE (2023); patent on compound (2018), PE (2019); two patents on compound (2021), PE (2021); patent on method of treating thrombocytopenia (2021), PE (2021); patent on method of enhancing platelet production (2021), PE (2021); patent on method of enhancing platelet production (2023), PE (2023); patent on salt form (2025); PE (2026); five patents on formulation of different dose strengths (all 2027), PE (2028); ODE (2021), PE (2022, 2022). EU: Two patents on compound (2021; 2021), SPC for one compound patent (2025); patent on salt form (2023); patent on formulation (2027); RDP (2020). Japan: Patent on compound (2021), PTE (2025); patent on salt form (2023); PTE (2023), patent on formulation (2027); RDP (2020). There is currently no generic competition in the US, EU or Japan. In the US, a generic manufacturer has filed an ANDA challenging certain patents other than the compound patents. The EU formulation patent is being opposed in the EPO.

Votrient. US: Patent on compound (2021), PTE (2023), 2 patents on compound (2021, 2021), ODE (2019). EU: Patent on compound (2021), SPC (2025); RDP (2020). Japan: patent on compound (2021), PTEs (2025, 2026); RDP (2020). There is currently no generic competition in the US, EU or Japan.

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Jakavi. EU: Patent on compound (2026), SPC (2027); patent on salt (2028); RDP (2023). Japan: Patent on compound (2026), PTE (2028), PTE (2030); patent on salt (2028), PTE (2028), PTE (2030); patent on method of use (2026), PTE (2027); RDP (2022). There is currently no generic competition in the EU or Japan. The EU salt patent is being opposed in the EPO.

Kisqali (formerly LEE011). US: Three patents on compound (2028, 2030, 2031), pending PTE (2031); two patents on methods of use (2029, 2029); patent on salt (2031); RDP (2022). EU: Two patents on compound (2027, 2029), pending SPC (2032); patent on methods of use (2029); RDP (2027). Japan: Two patents on compound (2027, 2029). *Kisqali* is currently not marketed in Japan. There is currently no generic competition in the US or EU.

Rydapt (formerly PKC412). US: Three patents on methods of use (2022, 2024, 2030); RDP (2022), ODE (2024). EU: Two patents on methods of use (2022, 2024); patent on formulation (2020); RDP (2027). Japan: Two patents on methods of use (2022, 2024); patent on formulation (2020). *Rydapt* is currently not marketed in Japan. There is currently no generic competition in the US or EU.

Kymriah (formerly CTL019). US: Seven patents on cells and/or pharmaceutical compositions comprising the cells (all 2031); four patents on methods of use (all 2031); RDP (2029), PE (2030); ODE (2024), PE (2025). EU: Patent on cells and methods of use (2031). Japan: patent on pharmaceutical compositions (2031). *Kymriah* is currently not marketed in the EU or Japan. There is currently no generic competition in the US.

Novartis Pharmaceuticals Business Unit

Ophthalmology

Lucentis. EU: Two patents on compound (2018; 2018), one SPC (2022), RDP (2018). Japan: Patent on compound (2018), PTE for age-related macular degeneration (2019), PTE for pathologic myopia (2021), PTE for retinal vein occlusion (2023). There is currently no generic competition in the EU or Japan.

Duotrav, Travatan and *Travatan Z.*

Duotrav. EU: Six patents on formulations (2029). Japan: Patent on methods of use (2014), PTE (2018); two patents on formulations (2029). *Duotrav* is not marketed in the US. There is generic competition in some EU countries. There is currently no generic competition in Japan. In the EU, two formulation patents are being opposed in the EPO.

Travatan. EU: Six patents on formulations (2029). *Travatan* is not marketed in the US or Japan. There is generic competition in the EU. In the EU, two formulation patents are being opposed in the EPO.

Travatan Z. US: Three patents on formulations (2027; 2027; 2029). Japan: Three patents on formulation (2027). *Travatan Z* is not marketed in the EU. There is currently no generic competition in the US or Japan. In the US, Novartis has resolved patent litigation with certain generic manufacturers. In the US one formulation patent (2029) is being challenged in an IPR proceeding in the USPTO.

Immunology and Dermatology

Cosentyx. US: Patent on compound (2027), pending PTE (2029); patent on method of use (psoriasis) (2032); patent on method of use (ankylosing spondylitis) (2031); RDP (2027). EU: Patent on compound (2025), SPC (2030); patent on method of use (psoriasis) (2031); RDP (2026). Japan: Patent on compound (2025), PTE (2026, 2028, 2029); patent on method of use (2031), PTE (2032, 2033); RDP (2022). There is currently no generic competition in the US, EU, or Japan.

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

Xolair. US: Patent on compound (2018); patents on syringe formulation (2021, 2024). EU: Patents on syringe formulation (2021, 2024). Japan: Patents on syringe formulation (2021, 2024). There is currently no generic competition in the US, EU or Japan.

Ilaris. US: Patent on compound (2024); patent on method of use in cryopyrin-associated periodic syndromes (CAPS) (2026), patent on method of use in familial Mediterranean fever (FMF) (2026), patent on method of use in systemic onset juvenile idiopathic arthritis (SJIA) (2027), patent on method of use in hyperimmunoglobulin D syndrome (HIDS) and tumour necrosis factor receptor associated periodic syndrome (TRAPS) (2028); patent on formulation (2029); RDP (2021). EU: Patent on compound (2021), SPC (2024), PE (2025); patent on method of use in SJIA (2026), patent on method of use in FMF (2026), patent on formulation (2029); RDP (2020). Japan: Patent on compound (2021), PTE for CAPS (2024), PTE for FMF, HIDS and TRAPS (2026); patent on method of use in familial cold urticaria, neonatal onset multisystem inflammatory disease and FMF (2026), patent on formulation (2029); ODE for CAPS (2021); ODE for FMF, HIDS and TRAPS (2026).

Neuroscience

Gilenya. US: Patent on compound (2014), PTE (2019), pending PE (2019); patent on dose (2027). EU: Patent on compound (2013), SPC (2018); RDP (2021); patent on formulation (2024), SPC (2026). Japan: Patent on compound (2013), PTE (2018); RDP (2021); two patents on formulation (2024; 2024). There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging the compound patent. The US dose patent is being challenged in an IPR proceeding in the USPTO.

Respiratory

Xolair. The information set forth in the IP paragraph for *Xolair* under the *"Immunology and Dermatology"* heading also applies to *Xolair* for respiratory indications.

Cardio-Metabolic

Entresto. US: Four patents on combination (2023; 2023; 2023; 2023); two patents on complex (2026; 2027); RDP (2020). EU: Patent on combination (2023), SPC (2028); patent on complex (2026), SPC (2030); 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 is being opposed in the EPO.

Established Medicines

Galvus and *Eucreas*. EU: Patent on compound (2019), SPC (2022); patent on combination (2021), SPC (2022); patent on *Eucreas* formulation (2026). Japan: Patent on compound (2019), PTE on mono therapy and combinations with sulfonyureas (2024), PTE on mono therapy and combinations with other antidiabetics (2022) PTE on *Eucreas* combination (2024); patent on combination (2021); patent on *Galvus* formulation (2025), PTE (2025); patent on *Eucreas* formulation (2026), 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.

Exforge and *Exforge HCT.*

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Exforge: US: Patent on *Exforge* combination (2019). EU: Patent on *Exforge* combination/*Exforge HCT* combination (2019), SPC (2021). There is generic competition in the US, EU and Japan. The EU *Exforge* combination/*Exforge HCT* combination patent is being challenged in the EPO and in the patent offices of some EU countries. In the EU, Novartis has resolved patent litigation with certain generic manufacturers. We are taking steps to enforce the EU *Exforge* combination/*Exforge HCT* combination patent against generic manufacturers.

Exforge HCT: US: Patent on *Exforge HCT* combination (2023); patent on formulation (2023). EU: patent on *Exforge* combination/*Exforge HCT* combination (2019), SPC (2021); RDP (2019). Japan: Patent on *Exforge HCT* combination (2023). There is generic competition in the US. There is currently no generic competition in the EU. *Exforge HCT* is not currently marketed in Japan. The EU *Exforge* combination/*Exforge HCT* combination patent is being challenged in the EPO and in the patent offices of some EU countries.

Diovan and *Co-Diovan/Diovan HCT. Diovan*: There is generic competition in the US, EU and Japan. *Co-Diovan/Diovan HCT*: There is generic competition in the US, EU and Japan.

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

Exelon and *Exelon* Patch.

Exelon: There is no patent protection for *Exelon* capsules in the US or EU. There is generic competition in the US and EU.

Exelon Patch: US: Patent on formulation (2019). EU: Patent on formulation (2019). Japan: Patent on formulation (2019), PTE (2023); RDP (2019). There is generic competition in the US and in most EU countries. There is currently no generic competition in Japan. In the US Novartis has resolved patent litigation with certain generic manufacturers.

Compounds in Development

We provide the following information for non-marketed compounds in development that have been filed with the FDA and/or the EMA for registration but have not yet been approved by either agency for any indication.

AMG 334. US (to be co-commercialized with Amgen): Patent on compound (2031). EU: Patent on compound (2029).

SANDOZ

Our Sandoz Division is a global leader in generic pharmaceuticals and biosimilars and sells products in more than 150 countries. In 2017, the Sandoz Division achieved consolidated net sales of $10.1 billion, representing 21% of the Group's total net sales. Sandoz develops, manufactures and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients.

Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals. 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 cardiovascular, central nervous system, dermatology, gastrointestinal and hormonal therapies, metabolism, oncology, ophthalmics, pain, and respiratory, as well as finished dosage form anti-infectives sold to third parties. In Anti-Infectives, Sandoz manufactures and supplies 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, including biosimilars, and provides biotechnology manufacturing services to other companies.

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Sandoz products were estimated to reach more than 500 million patients worldwide in 2017 and Sandoz strategy is to further increase patient access by driving sustainable and profitable growth. Sandoz executes on its divisional strategy by focusing on several key priorities, including investing in key markets and therapeutic areas, increasing the performance of its small-molecule Development and Regulatory organization and maximizing opportunities in biosimilars. Sandoz focuses on products that add more value for patients, payors and healthcare professionals than standard generics.

Top marketed products in the Sandoz generic medicines portfolio include broad-spectrum antibiotic amoxicillin/clavulanic acid, multiple sclerosis treatment *Glatopa* (glatiramer acetate injection) 20mg/mL, osteoporosis treatment zoledronic acid, hypokalemia treatment potassium, hyperthyroidism treatment levothyroxine sodium, oncology therapy cyclophosphamide, and pain medication fentanyl, which is delivered using a transdermal patch.

Sandoz also has a strong and continued strategic focus on biosimilars, which it began developing in 1996 and today sells in more than 80 countries. Sandoz is the market leader in biosimilars and now markets a total of five biosimilars. These biosimilars are: *Omnitrope*, a human growth hormone; *Binocrit,* an erythropoiesis-stimulating agent used to treat anemia; filgrastim for neutropenia under the brand names *Zarzio* outside the US and *Zarxio* in the US; *Rixathon* (biosimilar rituximab), approved in Europe in 2017 to treat blood cancers and immunological diseases (also approved in the EU as *Riximyo* under a duplicate marketing authorization); and *Erelzi* (biosimilar etanercept), approved in Europe in 2017 to treat multiple inflammatory diseases. Availability of these biosimilars varies by country.

The FDA approved biosimilar *Erelzi* (etanercept-szzs) in 2016 to treat multiple inflammatory diseases. A confirmatory clinical safety and efficacy study demonstrated that *Erelzi* is equivalent to reference medicine Enbrel®. The biosimilar launch in the US is pending litigation with Amgen, which markets Enbrel®.

Filings were accepted in the EU in 2017 for our biosimilar adalimumab, infliximab and pegfilgrastim, and in the US for our biosimilar rituximab in 2017 and adalimumab in 2018.

We plan to submit additional data for pegfilgrastim to the FDA in 2019 to address a complete response letter received from the FDA in June 2016.

According to IMS Health, as of November 2017, Sandoz holds the global number one position in sales of biosimilars and of generic anti-infectives, oncology and ophthalmic medicines. In addition, Sandoz holds leading global positions in key therapeutic areas including generic cardiovascular, central nervous system, gastrointestinal, metabolism, pain and respiratory medicines.

In 2017, product launches in the US included olopatadine hydrochloride 0.2% ophthalmic solution, an authorized generic version of *Pataday* (olopatadine hydrochloride ophthalmic solution) and sevoflurane (Ultane®).

An Abbreviated New Drug Application (ANDA) for *Glatopa* (glatiramer acetate injection) 40mg/mL was filed with the FDA in February 2014. However, the FDA approval and commercial launch of *Glatopa* 40mg/mL has been delayed in connection with an FDA Warning Letter received by Pfizer in February 2017 related to the Pfizer manufacturing plant at McPherson, Kansas. Pfizer is the contract manufacturer for the fill and finish stage of *Glatopa* 40mg/mL production at its McPherson site. The FDA re-inspected the Pfizer McPherson site in the fourth quarter of 2017 and issued Form 483 observations. In response, Pfizer proposed corrective and preventive actions to the FDA. The FDA is reviewing Pfizer's response and we await the conclusion of the FDA's assessment. Under FDA policy, approval of the Abbreviated New Drug Application for *Glatopa* 40mg/mL is dependent in part on the satisfactory resolution of the FDA's observations for the Pfizer facility where the final product is made. Therefore, the date of commercial availability of *Glatopa* 40mg/mL is not yet known.

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In 2017, product launches in various European countries included tenofovir disoproxil fumarate (Gilead's Viread®), emtricitabine/tenofovir disoproxil fumarate (Gilead's Truvada®) and etoricoxib (MSD's Arcoxia®).

Following an internal reorganization announced on January 27, 2016, nineteen mature products were transferred from our Innovative Medicines Division to the Retail Generics franchise of Sandoz.

Sandoz also holds operational responsibility for the Novartis Access program. Novartis Access offers a portfolio of medicines to treat chronic diseases in low- and lower-middle income countries. The portfolio addresses cardiovascular diseases, type 2 diabetes, respiratory illnesses and breast cancer, and is offered to governments, non-governmental organizations (NGOs) and other public sector health providers for one US dollar per treatment per month. Effective as of April 1, 2016, operational control for the Novartis Malaria Initiative, our largest access-to-medicine program, was transferred from our Innovative Medicines Division to Sandoz. As of the end of 2016, these two programs were integrated in the Novartis Social Business unit, which also comprises the Novartis Healthy Family programs, Sandoz NGO Supply and SMS for Life.

New Products

Sandoz launched a number of products in various countries in 2017, including:

Emtricitabine/tenofovir disoproxil fumarate (Gilead's Truvada®)

Etoricoxib (MSD's Arcoxia®)

Olopatadine hydrochloride 0.2% ophthalmic solution (*Pataday*)

Sevoflurane (AbbVie's Ultane®)

Tenofovir disoproxil fumarate (Gilead's Viread®)

Key Marketed Products

Sandoz markets approximately 1000 molecules in countries around the world. The following are some of the Sandoz key marketed products in each of its franchises (availability varies by market):

Retail Generics

Product	Originator Drug	Description
Amoxicillin/clavulanic acid	Augmentin®	Antibiotic
Zoledronic acid	*Aclasta*	Osteoporosis treatment
Potassium	Klor-Con®	Hypokalemia treatment
Levothyroxine sodium	Synthroid®; Levoxyl®	Hypothyroidism treatment
Cyclophosphamide	Endoxan®	Breast, ovarian and non-small cell cancer treatment
Fentanyl	various	Pain treatment

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

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

Biopharmaceuticals

Product	Originator Drug	Description
Omnitrope	Genotropin®	Recombinant human growth hormone
Binocrit and Epoetin alfa *Hexal*	Eprex®/Erypo®	Recombinant protein used for anemia
Zarzio, *Zarxio* and Filgrastim *Hexal*	Neupogen®	Recombinant protein used in oncology
Glatopa	Copaxone® 20 mg/mL	Multiple sclerosis treatment
Erelzi	Enbrel®	Treatment for multiple inflammatory diseases
Rixathon	MabThera®	Treatment for blood cancers and immunological diseases

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[1]	Common name	Mechanism of action	Potential indication/ indications	Therapeutic areas	Route of administration	Current phase
GP1111	infliximab	TNF-α inhibitor	Inflammatory bowel disease, rheumatoid arthritis and plaque psoriasis (same as originator)	Immunology	Intravenous	EU: Registration
GP2013	rituximab	Anti-CD20 antibody	Non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis, and microscopic polyangiitis (same as originator)	Oncology and Immunology	Intravenous	EU: Approved US: Registration
GP2017	adalimumab	TNF-α inhibitor	Arthritides (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis), plaque psoriasis and others (same as originator)	Immunology	Subcutaneous	EU: Registration US: Registration
LA-EP2006	pegfilgrastim	Pegylated granulocyte colony-stimulating factor	Chemotherapy-induced neutropenia and others (same as originator)	Oncology	Subcutaneous	EU: Registration US: III[2]

(1) HX575 epoetin alfa project retired in US due to change in prioritization.

(2) Resubmission planned for 2019 to address FDA complete response letter received June 2016.

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Principal Markets

The two largest generics markets in the world the US and Europe are the principal markets for Sandoz. The following table sets forth the aggregate 2017 net sales of Sandoz by region:

Sandoz	2017 Net Sales to third parties	
	$ millions	%
Europe	4,633	46
United States	3,278	33
Asia, Africa, Australasia	1,391	14
Canada and Latin America	758	7
Total	**10,060**	**100**
Of which in Established Markets*	7,383	73
Of which in Emerging Growth Markets*	2,677	27

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

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

Production

The 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 and quality standards. 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 our products at facilities worldwide. See also " Item 4.D Property, Plants and Equipment." 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 with quality as a primary goal within our own production network. Those processes include fermentation, chemical syntheses and precipitation processes, as well as sterile processing. Many biologic medicines 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, and to review and adapt our manufacturing network to meet the needs of our Sandoz Division.

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.

Because the manufacture of our products is complex and heavily regulated by governmental health authorities, supply is never guaranteed. If we or our third party suppliers fail to comply with applicable

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regulations then there could be a product recall or other shutdown or disruption of our production activities. We have experienced supply interruptions for our products 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. 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 always be able to successfully manage such issues when they arise.

Please refer to " Item 4.B Business Overview Sandoz" above for more detailed information regarding the manufacture of *Elatopa* 40mg/mL.

In October 2015, our Sandoz Division 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 were 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. In July 2017, the FDA confirmed that it closed out the October 2015 Warning Letter with respect to our Kalwe and Turbhe sites.

In September 2015, the FDA confirmed that it closed out the May 2013 Warning Letter relating to our Sandoz Division 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.

Marketing and Sales

Sandoz sells a broad portfolio of products, including the products of our Retail Generics franchise 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 versions of originator pharmaceutical products, such as those sold by our Retail Generics franchise. 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.

Recent trends have been toward continued consolidation among distributors and retailers of Sandoz products, both in the US and internationally, which has increased our customers' purchasing leverage. In addition, Sandoz faces increased competition from other manufacturers of generic medicines in the US. These factors have resulted in increased industry-wide pressure on prices for generic products, particularly in the US, which contributed to a decline in US sales in 2017. Moreover, we are exposed to increased concentration of credit risk as a result of the consolidation among our customers.

Legislative or regulatory changes can have a significant impact on our business in a country. In Germany, for example, the generic market has experienced a major transition and healthcare reforms have increasingly shifted decision making from physicians to insurance funds.

Our Anti-Infectives franchise supplies active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to the pharmaceutical industry worldwide.

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

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markets our biosimilar products are marketed as branded competitors to the originator products. However, a June 2017 US Supreme Court ruling has clarified certain aspects of the US biosimilar approval pathway under the Biologics Price Competition and Innovation Act (see " Regulation Biosimilars" for additional information).

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 encouraged more generic product launches, resulting in increased competition among the companies selling generic pharmaceutical products, leading to ongoing price pressure. In particular, Sandoz faces increased industry-wide pressure on prices for generic products, particularly in the US, driven by factors including customer consolidation and growing competition from other manufacturers of generic medicines. These factors contributed to a decline in US sales in 2017.

In addition, research-based pharmaceutical companies are participating directly in the generic conversion process by licensing their patented products to generic companies (so-called "authorized generics"). Consequently, generic companies that were not otherwise in a position to launch a specific product may enter the generic market using the innovator's product. In the US, the authorized generic is not subject to the Hatch-Waxman Act rules regarding exclusivity (see " Regulation"), which means that the company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder. Authorized generics serve as a business opportunity for Sandoz when the product of a research-based pharmaceutical company loses patent protection and Sandoz secures a license from the research-based pharmaceutical company to launch the authorized generic of that product. Authorized generics can also reduce the ability of the generic exclusivity holder to recoup its investment in creating the first generic medicine to compete with the originator product.

Development and Registration

Development of Sandoz Biopharmaceuticals products is jointly overseen by Sandoz and by Novartis Global Drug Development. Development and registration activities for Retail Generics products, and certain registration activities for Biopharmaceuticals products, continue to be overseen directly by Sandoz.

Before a generic pharmaceutical may be marketed, intensive technical and clinical development work must be performed to demonstrate, in bioavailability studies, the bioequivalence 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, generic pharmaceutical products can be offered for sale at prices often much lower than those of products protected by patents and data exclusivity, which must recoup substantial 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 biological reference medicine. Due to the inherent variability and complexity of biologic products, including batch-to-batch differences and variations following manufacturing changes, the development and the regulatory pathway of biosimilars differ significantly from that of generics.

The development of a biosimilar product is much more technically challenging than the development of a typical generic pharmaceutical. While generic pharmaceuticals normally do not require clinical studies in patients, regulators worldwide do require such targeted studies for biosimilar products. Biosimilars are engineered to match the reference medicine in quality, safety and efficacy. This is achieved by systematically defining the target range of the reference medicine and then comparing the biosimilar to

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the reference medicine 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 to establish efficacy and safety de novo, the clinical studies required are less than those required for a reference biologic. Therefore, the cost of development for a biosimilar is usually less than that of a reference biologic.

The Development and Registration staff employed by affiliates of the Sandoz Division are based worldwide, including facilities in Holzkirchen, Germany; Rudolstadt, Germany; Unterach, Austria; Melville, New York; Hicksville, New York; and Boucherville, Canada. In 2017, Sandoz expensed $0.8 billion in product development, which amounted to 8% of the division's net sales. Sandoz expensed $0.8 billion in 2016 and $0.8 billion in 2015. For additional information, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis."

Regulation

Generics

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 reference products, so long as the generic version could be shown in bioequivalence 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 holder of the marketing authorization for the reference product, 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 patents on the reference product. 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 " Innovative Medicines 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 innovator company for the reference product, 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 company 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

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pre-clinical and clinical trials filed by the innovator company that show a significant clinical benefit in comparison to the existing therapies.

Biosimilars

The regulatory pathways for approval of biosimilar medicines are still 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 the US, while the WHO has issued guidance. Sandoz has successfully registered and launched the first biosimilar (or biosimilar type) medicine in Europe, the US, Canada, Japan, Taiwan, Australia and many countries in Latin America and Asia. Sandoz was the first company to secure approval for and launch a biosimilar under the US biosimilar pathway that was established as part of the Biologics Price Competition and Innovation Act (BPCIA).

The approval of biosimilars in Europe follows a process similar to that followed for small molecules. 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 reference medicine 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 medicine and the biosimilar.

In the US, under the BPCIA, a biosimilar must be highly similar with no clinically meaningful differences compared to the reference medicine. 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 ongoing litigation. A ruling by the US Supreme Court in June 2017 clarified several key issues regarding the patent dispute resolution mechanisms in the BPCIA, including that the biosimilar medicine applicant can provide notice of its intention to commercially market its biosimilar (called the Notice of Commercial Marketing or NCM) to the originator company for the reference medicine at any time, including before FDA approval of the biosimilar medicine. The Court also clarified that a biosimilar applicant cannot be compelled by federal injunction to either provide the NCM or to participate in the patent dispute resolution procedures under the BPCIA (also known as the "patent dance"). The Court remanded this matter to the US Federal Circuit, which in December 2017 determined that such an injunction also is not available under state laws, as the federal BPCIA preempts state laws on this issue.

Intellectual Property

We take all reasonable steps to ensure that our products do not infringe valid intellectual property rights held by others. Nevertheless, competing companies commonly assert patent and other intellectual property rights. As a result, we can become involved in significant 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 potentially substantial damages.

Wherever possible, our 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. However, 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.

ALCON

Our Alcon Division researches, develops, manufactures, distributes and sells eye care products. Alcon is a global leader in eye care with product offerings in eye care devices and vision care. Its products are

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sold in more than 140 countries. In 2017, the Alcon Division had consolidated net sales of $6.0 billion representing 12% of total Group net sales.

To meet the needs of patients, ophthalmologists, surgeons, optometrists, opticians and physician specialists, Alcon operates with two global business franchises: Surgical and Vision Care. Each business franchise operates with specialized sales forces and marketing support.

Following an internal reorganization announced on January 27, 2016, Alcon's Ophthalmic Pharmaceuticals products were transferred to our Innovative Medicines Division.

In early 2017, we announced a strategic review of the Alcon Division in order to explore all options to maximize value for our shareholders. We have made significant progress in our ongoing strategic review and have examined all options, ranging from retaining the business to a capital markets solution (e.g., an IPO or a spin-off). As part of this, we have updated Alcon's strategic plan which confirms that it has the potential to grow sales at or above market while delivering profitability at least in line with the industry. We have also made significant progress on developing a potential capital markets solution, including financial carve-outs, tax and legal entity structuring, and identifying listing and incorporation locations. Key criteria for a final decision and timing remain continued Alcon sales growth and margin improvement which need to be demonstrated for multiple quarters leading to potential action not likely before the first half of 2019.

In addition, we transferred our over-the-counter ophthalmic products and certain surgical diagnostic products (2017 sales of approximately $0.8 billion) from the Innovative Medicines Division to the Alcon Division effective January 1, 2018. Our prescription Ophthalmic medicines business remains with the Innovative Medicines Division. In compliance with IFRS, beginning with our first quarter 2018 results, Novartis will update its segment financial information to reflect this transfer, both for the current and prior years, to aid comparability of year-on-year results.

In April 2016, Alcon entered into a strategic alliance with PowerVision to develop an accommodating IOL that has the potential to change focus via a fluid-driven shape-changing technology.

In March 2016, Alcon acquired Transcend Medical, the developer of *CyPass* micro-stent, a micro invasive glaucoma surgery (MIGS) device to treat patients with glaucoma. The *CyPass* micro-stent was initially launched in the US in October 2016.

In February 2016, Alcon entered into an exclusive agreement in the field of ophthalmology with TrueVision to distribute *NGENUITY*, a 3D visualization system which combines a high-dynamic 3D camera, advanced high-speed image optimization, polarizing surgeon glasses, and an ultra-high definition 4K OLED 3D display to create a platform for digitally assisted vitreoretinal surgery to help improve visualization of the delicate tissues in the back of the eye.

Alcon Division Products

Surgical

Our Alcon Division's Surgical franchise is the leader in global ophthalmic surgical product sales, offering ophthalmic surgical equipment, instruments, disposable products and intraocular lenses for use in surgical procedures to address cataracts, vitreoretinal conditions, glaucoma and refractive errors.

The Alcon Surgical portfolio includes intraocular lenses (IOLs) and equipment for use in cataract procedures, devices for use in vitreoretinal surgeries, surgical equipment and diagnostic devices used in refractive surgical procedures, and devices for use in treating patients with glaucoma. Our IOLs include the *AcrySof* family of IOLs, with options ranging from monofocal IOLs for basic cataract surgery to specialized IOLs for the correction of presbyopia and astigmatism at the time of cataract surgery; the recently launched *Clareon* monofocal IOL, made of a new material with an advanced design that enables sharp, crisp vision, low edge glare, and outstanding optic clarity; and the *UltraSert* and *AutonoMe*

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innovative IOL delivery systems. The Cataract Refractive Suite by Alcon features the *Centurion* vision system for phacoemulsification and cataract removal; the *Infiniti* vision system for phacoemulsification and cataract removal; the *LenSx* femtosecond laser used for specific steps in the cataract surgical procedure; the *LuxOR* ophthalmic microscope; the *ORA SYSTEM* for cataract surgery planning and intra-operative guidance during surgery; and the *Verion* imaged guided system for use during cataract surgery. The Alcon vitreoretinal portfolio includes the *NGENUITY* 3D visualization system, designed to enhance visualization of the back of the eye, and the *Constellation* vision system. Our *WaveLight* devices are used for LASIK and other vision-correcting refractive procedures, including topography-guided procedures marketed under the *Contoura* brand. The Alcon glaucoma device portfolio includes the *CyPass* micro-stent, a micro invasive glaucoma surgery device, and the *EX-PRESS* glaucoma filtration device. In addition, Alcon provides advanced viscoelastics, irrigating solutions, diagnostic ophthalmic products, surgical packs and other disposable products for cataract and vitreoretinal surgery.

Vision Care

Our Alcon Division's Vision Care franchise develops and markets contact lenses and lens care products and over-the-counter ophthalmic products. Alcon's broad portfolio of silicone hydrogel, daily disposable and color contact lenses includes our *Air Optix*, *Dailies* and *Freshlook* brands. Our *Dailies* product line includes the *Dailies Total1* lens, a first-of-its-kind water gradient contact lens, which is also offered in a multifocal option for patients with presbyopia. Our *Air Optix* monthly replacement product line features silicone hydrogel contact lenses in monofocal, astigmatism-correcting, and multifocal options, as well as *Air Optix Colors* and *Air Optix* plus *HydraGlyde* contact lenses. Our contact lens care solutions business includes the *Opti-Free* line of multi-purpose disinfecting solutions, as well as the *Clear Care* and *AOSEPT Plus* line of hydrogen peroxide lens care solutions. Over-the-counter ophthalmic products that have moved from our Innovative Medicines Division to the Alcon Vision Care franchise include artificial tear and related dry eye products marketed under the *Systane*, *Tears Naturale*, and *Genteal* brands; *Naphcon A* and *Zaditor* eye drops for the temporary relief of ocular itching due to allergies; and vitamins for ocular health marketed under the *ICAPS* and *Vitalux* brands.

New Products

We received a number of approvals and launched a number of products in 2017, including:

CyPass micro-stent, a micro invasive glaucoma surgery device, received a CE Mark and was launched in the EU for the treatment of patients with mild to moderate primary open-angle glaucoma in conjunction with cataract surgery. In addition, the *CyPass* micro-stent has a CE Mark for use as a standalone procedure in patients with primary open-angle glaucoma who have failed previous medical treatments.

AcrySof IQ *ReSTOR* +2.5D Toric IOL, was approved by the FDA and launched in the US to address presbyopia and astigmatism at the time of cataract surgery. This IOL features the *ACTIVEFOCUS* optical design, to delivers crisp, clear distance vision as well as a range of vision for patients who desire less dependence on glasses.

The *Clareon* monofocal IOL received a CE Mark and was launched in the EU. This IOL utilizes a new material and features an advanced design that enables sharp, crisp vision, low edge glare, and outstanding optic clarity. The *Clareon* monofocal IOL was launched with the new automated, disposable *AutonoMe* pre-loaded IOL delivery system.

Systane Complete lubricant eye drops received a CE Mark. This addition to the *Systane* product line offers fast hydration and long-lasting relief, with nano-droplet technology for enhanced coverage. We expect to launch *Systane* Complete in the EU in 2018.

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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 IOLs, including:
	AcrySof IQ monofocal IOLs
	AcrySof IQ Toric astigmatism-correcting IOLs
	AcrySof IQ *ReSTOR* presbyopia-correcting IOLs
	AcrySof IQ *ReSTOR* Toric presbyopia- and astigmatism-correcting IOLs
	AcrySof IQ *PanOptix* presbyopia-correcting IOLs
	AcrySof IQ *PanOptix* Toric presbyopia- and astigmatism-correcting IOLs
	Cataract Refractive Suite by Alcon, including:
	Centurion vision system for phacoemulsification and cataract removal
	Infiniti vision system for phacoemulsification and cataract removal
	LenSx femtosecond laser used for specific steps in the cataract surgical procedure
	LuxOR ophthalmic microscope
	ORA SYSTEM for cataract surgery planning and intra-operative guidance during surgery
	Verion imaged-guided system for use during cataract surgery
	Clareon monofocal IOL with the automated, disposable *AutonoMe* pre-loaded IOL delivery system
	UltraSert pre-loaded IOL delivery system
Vitreoretinal	*Constellation* vision system for vitreoretinal operations
	Grieshaber surgical instruments
	NGENUITY 3D visualization system
	Purepoint laser system and probes
	Ultravit vitrectomy probes
Refractive	*WaveLight EX500* excimer laser for LASIK and other refractive correction procedures
	WaveLight FS200 femtosecond laser for refractive surgery
Glaucoma	*CyPass* micro-stent for the treatment of mild to moderate primary open angle glaucoma
	EX-PRESS glaucoma filtration device

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

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Vision Care

Contact Lenses	*Air Optix* family of silicone hydrogel contact lenses (including *Air Optix Colors* and *Air Optix* plus *HydraGlyde* lenses) *Dailies* family of daily disposable contact lenses (including *Dailies Total1* lenses) *FreshLook* family of color contact lenses
Contact Lens Care	*Clear Care* family of hydrogen peroxide lens care solution (*AOSEPT Plus* outside of North America) *Opti-Free* family of multi-purpose disinfecting solution
Dry Eye	*Genteal* family of artificial tears *Systane* family of artificial tears and related dry eye products *Tears Naturale* lubricant eye drops
Allergy	*Naphcon A* for the temporary relief of ocular redness and itching due to allergies *Zaditor* for the temporary relief of ocular itching due allergies
Vitamins	*ICAPS* family of eye vitamin products *Vitalux* family of eye vitamin products

Selected Development Projects

The following tables provide an overview of certain key projects currently in development within our Alcon Division for the US and/or the EU. Alcon also has projects in development for markets outside the US and the EU, as well as less significant projects in development for markets throughout the world, including the US and EU. The planned submission dates in the tables below refer to the primary regulatory filings for each of the development projects listed. Full commercialization may be affected by other factors, including the potential need for additional regulatory filings, reimbursement status, and time to build product inventory. The term "Advanced" under the Current Phase in the tables below refers to a project for which a positive proof of concept has been established, and clinical and non-clinical studies are being conducted to establish the device's safety, efficacy or performance, which are needed to address regulatory requirements for obtaining marketing authorization.

Surgical

Project/Product	Description	Product Category	Planned Submission	Current Phase
A02238	Mid-tier phacoemulsification device	Cataract Equipment	US 2018 EU 2018	Advanced Advanced
AcrySof IQ *PanOptix* IOL	Presbyopia-correcting trifocal IOL	Cataract Implant	US 2019	Advanced
AcrySof IQ *PanOptix* Toric IOL	Presbyopia-correcting trifocal IOL for astigmatism	Cataract Implant	US 2019	Advanced

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Project/Product	Description	Product Category	Planned Submission	Current Phase
Clareon IOL with the *AutonoMe* pre-loaded delivery device	Next-generation IOL in automated pre-loaded delivery system	Cataract Implant	US 2019	Advanced
A02062	Extended depth of focus IOL	Cataract Implant	US 2019 EU 2019	Advanced Advanced
A02972	Digital visualization system connected with *Constellation* vision system	Vitreoretinal Equipment	US 2018 EU 2018	Advanced Advanced

Vision Care

Project/Product	Description	Product Category	Planned Submission	Current Phase
Systane Complete	Lubricant eye drop with nano-droplet technology	Dry Eye	US 2018	Advanced
A00717	Daily disposable line extension	Contact Lens	EU 2018 US 2018	Advanced Advanced
A01660	New daily disposable lens	Contact Lens	EU 2018 US 2018	Advanced Advanced
A02491	New monthly disposable lens	Contact Lens	EU 2020 US 2020	Advanced Advanced
A02931	New weekly disposable lens	Contact Lens	EU 2020 US 2020	Advanced Advanced

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 2017 net sales of the Alcon Division by region:

Alcon	2017 Net Sales to third parties	
	$ millions	%
Europe	1,570	26
United States	2,541	42
Asia, Africa, Australasia	1,452	24
Canada and Latin America	461	8
Total	**6,024**	**100**
Of which in Established Markets*	4,694	78
Of which in Emerging Growth Markets*	1,330	22

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

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Sales of the vast majority of our Alcon Division products are not subject to material changes in seasonal demand. However, sales of certain of our Vision Care products, including those for allergies and dry eye, are subject to seasonal variation.

Research and Development

In 2017, our Alcon Division expensed $0.6 billion in research and development, which amounted to 9% of the Division's net sales. Alcon expensed $0.5 billion in research and development in each of 2016 and 2015. For additional information, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis."

Research and development activities for Alcon's Surgical franchise are focused on expanding intraocular lens capabilities to further improve surgical and refractive outcomes and on developing equipment and instrumentation for cataract, vitreoretinal, glaucoma and corneal 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, on lens care solutions that provide the safety, disinfecting and cleaning power needed to help maintain ocular health, and on products to address dry eye symptoms.

Alcon continues to seek opportunities to collaborate with third parties on advanced technologies for various ocular medical uses. These include the potential to provide accommodative contact and intraocular lenses for patients living with presbyopia.

Production

The products of our Alcon Surgical franchise are manufactured at facilities located in the US, Belgium, Switzerland, Ireland, Germany and Israel. The products of our Alcon Vision Care franchise are manufactured at facilities located in the US, Germany, Singapore, Malaysia, Indonesia, Belgium, and Spain. Manufacturing for most Alcon products is overseen directly by the Alcon Division. Alcon coordinates with Novartis Technical Operations where appropriate. 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 combination of these factors means that supply is never guaranteed.

Like some of our competitors, our Alcon Division faces manufacturing issues from time to time. 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 if and when they arise.

Marketing and Sales

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

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and an integrated customer relationship management system is in place in many markets. We also rely on direct-to-consumer marketing campaigns 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. 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. Over-the-counter lens care, dry eye, allergy and ocular vitamin products can be found in major drugstores, food, mass merchandising and optical retail chains globally, subject to country regulations.

Competition

The eye care industry is highly competitive and subject to rapid technological change and evolving industry requirements and standards. Our Alcon Division competes with a number of different companies across its two franchises 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 comprise a broad line of proprietary eye care products. Our principal competitors also sometimes form strategic alliances and enter into co-marketing agreements in an effort to better compete.

Regulation

Most of our Surgical products and many of our 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 regulatory bodies 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) for Class III devices, and a Pre-Market Notification (510(k)) submission for Class II devices. Under a PMA, the manufacturer must submit to the FDA supporting evidence sufficient to prove the safety and effectiveness of the device. Under a 510(k) submission, the manufacturer notifies the FDA that it intends to commence marketing the product, with data that establishes the product as substantially equivalent to another Class II product already on the market.

In the EU, CE marking is required for all medical devices sold. By affixing the CE Mark, 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 ISO 13485.

Many of our Vision Care dry eye and allergy products are regulated as over-the-counter pharmaceuticals in the US, and several Surgical diagnostic ophthalmic products are regulated as prescription pharmaceuticals in the US and the EU. In the US, over-the-counter pharmaceuticals that comply with the FDA over-the-counter monograph regulations may be marketed without prior FDA approval. Alcon's prescription pharmaceutical products are subject to the same regulatory approval procedures as the prescription pharmaceutical products of our Innovative Medicines Division. See " Innovative Medicines Regulation."

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Price Controls

The prices of our Surgical devices are subject to reimbursement programs and price control mechanisms that vary from country to country. Due to increasing political pressure and governmental budget constraints, we expect these programs and mechanisms to remain robust and to potentially even be strengthened. As a result, such programs and mechanisms could have a negative influence on the prices we are able to charge for our Surgical products, particularly those used in cataract, glaucoma, and vitreoretinal surgeries.

For example, in India, the National Pharmaceutical Pricing Authority (NPPA) recently began imposing 75% to 85% price reductions on coronary stents (implantable medical devices intended to ensure an adequate flow of blood to the heart). The NPPA has begun to evaluate prices on other categories of medical devices, including IOLs used in cataract surgeries. If the Indian NPPA chooses to impose similar price reductions on IOLs from Alcon, this could have a negative impact on our Surgical franchise sales in India. It is also possible that regulatory agencies in other countries will consider applying similar price controls on IOLs and other Surgical products sold by Alcon.

Intellectual Property

We attach great importance to intellectual property including patents, regulatory exclusivities, trademarks, copyrights, know-how and research data in order to protect our investment in research and development, manufacturing and marketing. In general, we seek intellectual property protection under applicable laws for significant product developments in major markets. Among other things, patents may cover the products themselves, the processes for manufacturing a product, and particular uses of a product.

The protection offered by our intellectual property extends for varying periods depending on its legal life in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of intellectual property and its scope of coverage. We monitor infringements of our intellectual property and typically challenge such infringements. We also defend challenges through litigation and administrative proceedings to the validity of our intellectual property. However, because the outcomes of intellectual property challenges can be difficult to predict, there can be no assurance that we will be able to successfully protect our intellectual property rights in all cases. If we are unsuccessful in defending such challenges, we may face loss of exclusivity and increased competition in the affected territories. See generally " Innovative Medicines 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.

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 to the protection of our investment in the sales and marketing of our Surgical 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.

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4.C Organizational Structure

See "Item 4. Information on the Company Item 4.A History and Development of Novartis," and "Item 4. Information on the Company Item 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, or have entered into long-term lease arrangements for them. Some of our principal facilities are subject to mortgages and other security interests granted to secure indebtedness to certain financial institutions.

Novartis Technical Operations manages the production and supply chains of our Innovative Medicines and Sandoz Division products through a network of 68 manufacturing sites, as well as through external suppliers, and warehouse and distribution centers. Our 15 Alcon Surgical and Vision Care manufacturing sites continue to be managed by the Alcon Division.

The following table sets forth our major headquarters and most significant production, research and development and administrative facilities. See also " Item 4.B Business Overview Innovative Medicines Production," " Item 4.B Business Overview Sandoz Production" and " Item 4.B Business Overview Alcon Production" for a discussion of our manufacturing processes.

Major facilities

Location	Size of Site (in square meters)	Major Activity
Basel, Switzerland St. Johann	724,000*	Global Group headquarters, global Innovative Medicines Division headquarters, research and development, production of drug substances and drug intermediates
Kundl and Schaftenau, Austria	480,000	Production of biotechnological products, anti-infectives, active drug substances, product development
East Hanover, New Jersey	391,000	Innovative Medicines Division US headquarters, research and development
Barleben, Germany	340,000	Production of broad range of finished dosage forms
Fort Worth, Texas	325,000	Alcon Division headquarters, production, research and development for Alcon Vision Care, Surgical franchises

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Location	Size of Site (in square meters)	Major Activity
Changshu (Suzhou), China	230,000	Technical research, development and manufacturing of drug substances and drug intermediates
Cambridge, Massachusetts	205,000	Research and development
Shanghai, China	106,500	Research and development
Ringaskiddy, Ireland	85,000	Production of drug substances and drug intermediates
Johns Creek, Georgia	83,200	Production, research and development for Alcon Vision Care franchise
Ljubljana, Slovenia	83,000	Production of broad range of finished solid and sterile dosage forms
Grosswallstadt, Germany	82,400	Production, research and development for Alcon Vision Care franchise
Hyderabad, India	80,500	General administrative and development global service center
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
Holzkirchen, Germany	64,200*	Sandoz Division headquarters, production of oral films, transdermal delivery systems, matrix patches, product development
Grimsby, UK	64,000	Production of drug substances and drug intermediates
Puurs, Belgium	55,000	Production for ophthalmic medicines and Alcon Surgical franchise
Stryków, Poland	45,000	Production of broad range of bulk oral solid forms

Cork, Ireland	44,800	Production for Alcon Surgical franchise

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Location	Size of Site (in square meters)	Major Activity
Rudolstadt, Germany	44,000	Development and production of respiratory technologies and ophthalmics
Rueil-Malmaison, France	43,700*	Administrative offices for Innovative Medicines and Alcon
Johor, Malaysia	43,300	Production for Alcon Vision Care franchise
Irvine, California	39,700	Production, research and development for Alcon Surgical franchise
Houston, Texas	37,400	Production for Alcon Surgical franchise
Huningue, France	35,000	Production of drug substances for clinical and commercial supply
Singapore	35,000	Production for Alcon Vision Care franchise
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
Huntington, West Virginia	27,500	Production for Alcon Surgical franchise
Tokyo, Japan	26,000	Administrative offices for Innovative Medicines, Sandoz and Alcon
Sinking Spring, Pennsylvania	21,800	Production for Alcon Surgical franchise
Batam, Indonesia	21,500	Production for Alcon Vision Care franchise
Morris Plains, New Jersey	15,600	Production for Innovative Medicines Division cell & gene therapies

Princeton, New Jersey	14,300	Sandoz Division US headquarters

*

Change in reported size of site from 2016 Annual Report on Form 20-F primarily due to updates to internal real estate databases.

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To support the objectives of Novartis Technical Operations, we are progressing with our network transformation project, under which we are reviewing our manufacturing network to ensure it can appropriately meet the future needs of the Group. As part of our initial plans under this project, we previously announced the exit of our Sandoz Division plant in Hicksville, New York. This planned exit is currently on hold pending an assessment of our strategy for the site as part of the wider network review. We now expect the previously announced exit of our Sandoz Division site in Turbhe, India to be completed in 2018. In May 2017, we announced the planned closure of one manufacturing building at each of our Basel, Switzerland and Schweizerhalle, Switzerland sites by 2019. In October 2017, we announced our plan to close commercial production operations at our Broomfield, Colorado site over a two year period with production anticipated to conclude by the fourth quarter of 2019. In November 2017, we announced our plan to exit our packaging operations in Wehr, Germany by 2022.

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 Innovative Medicines 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 project included 17 new buildings, eight of them laboratory buildings. As of the end of 2017, the Campus project is substantially complete. Through December 31, 2017, the total amount paid on the Campus project is equivalent to $2.3 billion. These expenditures were funded from internally generated resources.

In 2012, Novartis announced the construction of a new state-of-the-art production facility to produce solid dosage form medicines for the Innovative Medicines Division in Stein, Switzerland. We expect our investment in this facility to exceed $660 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. Through December 31, 2017, the total amount paid and committed to be paid on this project is equivalent to $617 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 $750 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 2018 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, 2017, the total amount paid and committed to be paid on this project is equivalent to $723 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 now complete. Through December 31, 2017, the total amount paid on this project is $254 million.

The Alcon Division began an expansion of its Singapore facility in 2014 for contact lens manufacturing. The expansion has added 16,000 square meters of space for additional production lines. In 2017, Alcon began installation of a new contact lens manufacturing platform for certain products currently in development. Through December 31, 2017, the total amount paid and committed to be paid on this project is equivalent to $161 million.

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Environmental Matters

We integrate core values of environmental protection into our business strategy to protect the environment, 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 "Item 3. Key Information Item 3.D Risk Factors Environmental liabilities may adversely impact our results of operations." See also "Note 19. Provisions and other non-current liabilities" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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 pharmaceuticals and oncology medicines, generic and biosimilar medicines and eye care devices. Our mission is to discover new ways to improve and extend people's lives. Our vision is to be a trusted leader in changing the practice of medicine. Our strategy is to use science-based innovation to deliver better patient outcomes in growing areas of healthcare.

Following the completion of a series of transactions in 2014 and 2015, the Group's continuing operations comprise three global operating divisions, Innovative Medicines, Sandoz and Alcon. We also separately report the results of Corporate activities. The disclosure in this Form 20-F focuses on these continuing operations unless otherwise specified. 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 GSK Consumer Healthcare Holdings Ltd. for the period from March 2015 (the latter reported as an investment in associated companies). We sold on March 2, 2015, our Vaccines Division, excluding our influenza vaccines business, to GSK. Our influenza vaccines business was sold on July 31, 2015 to CSL and our Animal Health Division was sold on January 1, 2015 to Lilly.

Continuing Operations:

Innovative Medicines: Innovative patent-protected prescription medicines

Sandoz: Generic pharmaceuticals and biosimilars

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Alcon: Surgical and vision care products

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 the areas of each of our three divisions. To maintain our competitive positioning across these segments of the healthcare industry, we place a strong focus on innovating to meet the evolving needs of patients around the world, working to grow our presence in new and emerging markets, and to enhance our productivity to invest for the future and increase returns to shareholders. The financial results of our continuing 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 that are not attributable to specific segments such as certain revenues from intellectual property rights and certain expenses related to post-employment benefits, environmental remediation liabilities, charitable activities, donations and sponsorships.

In January 2018, we announced that Elizabeth (Liz) Barrett has been appointed CEO Novartis Oncology and a member of the ECN, effective February 1, 2018. Mrs. Barrett succeeds Bruno Strigini who decided to retire from Novartis for personal reasons.

In September 2017, we announced that Joseph Jimenez, CEO of Novartis, informed the Board of Directors of his desire to step down as CEO in 2018, after eight years in the position. The Board of Directors has appointed Vasant (Vas) Narasimhan, M.D., Global Head of Drug Development and Chief Medical Officer, as CEO of Novartis, effective February 1, 2018. Dr. Narasimhan is a member of the ECN and joined Novartis in 2005.

In August 2017, we announced that, effective January 1, 2018, Bertrand Bodson has been appointed to the new role of Chief Digital Officer, reporting to the CEO of Novartis. Mr. Bodson is responsible for creating and executing a company-wide digital strategy. As part of this strategy, we plan to improve the ways we use data in drug discovery and development, engage with patients, doctors and other stakeholders, as well as to automate business processes.

In early 2017, we announced a strategic review of our Alcon Division in order to explore all options to maximize value for our shareholders. We have made significant progress in our ongoing strategic review and have examined all options, ranging from retaining the business to a capital markets solution (e.g., an IPO or a spin-off). As part of this, we have updated Alcon's strategic plan which confirms that it has the potential to grow sales at or above market while delivering profitability at least in line with the industry. We have also made significant progress on developing a potential capital markets solution, including financial carve-outs, tax and legal entity structuring, and identifying listing and incorporation locations. Key criteria for a final decision and timing remain continued Alcon sales growth and margin improvement which need to be demonstrated for multiple quarters leading to potential action not likely before first half of 2019.

In addition, we transferred our over-the-counter ophthalmic products and certain surgical diagnostic products (2017 sales of approximately $0.8 billion) from the Innovative Medicines Division to the Alcon Division effective January 1, 2018. Our prescription Ophthalmic medicines business remains with the Innovative Medicines Division. In compliance with IFRS, beginning with our first quarter 2018 results, Novartis will update its segment financial information to reflect this transfer, both for the current and prior years, to aid comparability of year-on-year results.

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The Group is organized into three divisions, Innovative Medicines, Sandoz and Alcon, as well as Corporate activities. Our divisions are supported by the following cross-divisional organizational units: Novartis Institutes for BioMedical Research, Global Drug Development and Novartis Operations, which includes Novartis Technical Operations, Novartis Business Services and Novartis Corporate Affairs.

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, which conducts drug discovery research and early clinical development trials for our Innovative Medicines Division and also collaborates with our Sandoz Division. Approximately 6,000 full-time equivalent scientists and associates at NIBR are working to discover new medicines for various diseases at sites located in the US, Switzerland and China. For more information about NIBR, see "Item 4. Information on the Company Item 4.B Business Overview Innovative Medicines Research and Development Research program".

Our Global Drug Development (GDD) organization oversees all drug development activities for our Innovative Medicines Division and the biosimilars portfolio of our Sandoz Division. Development of products for the Surgical and Vision Care franchises within our Alcon Division and of small molecule generics for our Sandoz Division are not included in GDD. GDD works collaboratively with NIBR, Innovative Medicines and Sandoz to execute our overall pipeline strategy and takes an enterprise approach to pipeline portfolio management. GDD incorporates centralized global functions such as Regulatory Affairs and Global Development Operations, as well as Global Development units aligned with our business franchises. GDD was created to increase Group-wide coordination of drug development and to improve resource allocation, technology implementation and process standardization with a goal of further increasing innovation. GDD includes approximately 10,000 full-time equivalent associates worldwide.

Novartis Technical Operations (NTO) was established to centralize management of our manufacturing operations across our Innovative Medicines and Sandoz Divisions, with a goal of further improving efficiency. Manufacturing for Alcon's Surgical and Vision Care franchises continues to be managed by our Alcon Division. NTO is expected to optimize capacity planning and adherence to quality standards, and to 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. NTO includes approximately 26,900 full-time equivalent associates and 68 manufacturing sites across our Innovative Medicines and Sandoz Divisions.

Novartis Business Services (NBS), our shared service organization, delivers integrated solutions to all Novartis divisions and units worldwide. NBS seeks to drive efficiency and effectiveness across Novartis by simplifying and standardizing services across six service domains: human resources, real estate and facility services, procurement, information technology, commercial and medical support activities, and financial reporting and accounting operations. NBS has approximately 10,870 full-time equivalent associates in more than 50 countries. NBS works to leverage the full scale of Novartis to create value across the company and to free up resources to invest in innovation and our product pipeline. NBS continues to transfer the delivery of selected services to its five Global Service Centers in Dublin, Ireland; Hyderabad, India; Kuala Lumpur, Malaysia; Mexico City, Mexico; and Prague, Czech Republic.

In 2017, our Public Affairs and Group Country Management organizations were combined to form Novartis Corporate Affairs to better enable close collaboration among country presidents, unit heads and Public Affairs.

In 2017, Novartis continuing operations achieved net sales of $49.1 billion, while net income from continuing operations amounted to $7.7 billion. Of total net sales from continuing operations, $12.4 billion, or 25%, came from Emerging Growth Markets, and $36.7 billion, or 75%, came from Established Markets. Emerging Growth Markets comprise all markets other than the Established Markets

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of the US, Canada, Western Europe, Japan, Australia and New Zealand. Research & Development expenditure in 2017 amounted to $9.0 billion.

Headquartered in Basel, Switzerland, our Group companies employed 121,597 full-time equivalent associates as of December 31, 2017. Our products are sold in approximately 155 countries around the world.

Innovative Medicines Division

Our Innovative Medicines Division researches, develops, manufactures, distributes and sells patented prescription medicines to enhance health outcomes for patients and health-care providers. Innovative Medicines is organized into two global business units: Novartis Oncology and Novartis Pharmaceuticals. Novartis Pharmaceuticals consists of the global business franchises Ophthalmology, Immunology and Dermatology, Neuroscience, Respiratory, Cardio-Metabolic and Established Medicines.

In 2017, the Innovative Medicines Division accounted for $33.0 billion, or 67%, of Group net sales, and for $7.8 billion, or 87%, of Group operating income (excluding Corporate income and expense, net).

Sandoz Division

Our Sandoz Division develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical active substances that are not protected by valid and enforceable third-party patents. Sandoz is organized globally in three franchises: Retail Generics, Anti-Infectives, and Biopharmaceuticals. 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 cardiovascular, central nervous system, dermatology, gastrointestinal and hormonal therapies, metabolism, oncology, ophthalmics, pain, and respiratory, as well as finished dosage form anti-infectives sold to third parties. In Anti-Infectives, Sandoz manufactures active pharmaceutical ingredients and intermediates mainly antibiotics for internal use by Retail Generics and for sale to third party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

In 2017, Sandoz accounted for $10.1 billion, or 21%, of Group net sales, and for $1.4 billion, or 15%, of Group operating income (excluding Corporate income and expense, net).

Alcon Division

Our Alcon Division researches, develops, manufactures, distributes and sells eye care products. Alcon is a global leader in eye care with product offerings in eye care devices and vision care. Alcon is organized into two global business franchises: Surgical and Vision Care. The Surgical franchise 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. The Vision Care franchise 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 2017, Alcon accounted for $6.0 billion, or 12%, of Group net sales, and for $ 0.2 billion, or 2%, of Group operating income (excluding Corporate income and expense, net).

OPPORTUNITY AND RISK SUMMARY

The healthcare industry is entering a phase of exhilarating progress and change. Over the next two decades, we believe biomedical innovation will continue to accelerate spawning new treatments that will have unparalleled impact on humanity, with the potential to tame scourges like cancer and heart disease.

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The digital revolution that is now gaining momentum in healthcare is likely to transform everything from drug research and development to how doctors diagnose and treat diseases. These trends promise to help society address the changing healthcare needs of aging populations and produce better health outcomes for patients.

Our financial results are affected to varying degrees by external factors. Loss of market exclusivity and the introduction of branded and generic competitors could significantly erode sales of our innovative products. Our ability to grow depends on the success of our research and development efforts to replenish our pipeline, as well as on the commercial acceptance of our products in the markets. Increased pricing pressure could impact our ability to generate returns and invest for the future.

We have a significant global compliance program in place, but any failure to comply with local laws could lead to substantial liabilities. There are strict regulatory requirements surrounding our manufacturing processes, which introduce a greater chance for disruptions and liabilities. With products sold in approximately 155 countries, our ability to hedge against foreign exchange fluctuations could have a significant effect on our reported results. We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, and may incur significant impairment charges in the future. We pay taxes in numerous countries, and tax authorities around the world have increased their scrutiny of company tax filings. In addition, tax reform initiatives by the OECD, EU, Switzerland and the US, will require us to continually assess our organizational structure against tax policy trends, and could lead to an increased risk of international tax disputes and an increase in our effective tax rate, and could adversely affect our financial results. We may also fail to take advantage of rapid progress in digital technologies and in the development of new business models, and third parties may enter the healthcare field and could supplant our business.

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

RESULTS OF OPERATIONS

Novartis had solid performance in 2017 as strong sales of our growth drivers, including *Cosentyx* (secukinumab), *Entresto* (sacubitril/valsartan) and other recently launched products, continued to offset the impact of generic competition for our cancer treatment *Gleevec/Glivec*, which lost patent protection in the US and Europe during 2016. Our results underscore the breadth and strength of our product portfolio and highlight our success at steering through the patent expiration of one of our biggest-selling drugs.

Our divisions had varied results. Sales increased in the Innovative Medicines Division, and the Alcon eye care division returned to growth in 2017. Sandoz Division sales declined, as the effects of increased price competition in the US more than offset growth in the rest of the world.

Net sales for Novartis were $49.1 billion, up 1% in reported terms and up 2% measured in constant currencies (cc) to remove the impact of exchange rate movements. Sales volumes increased 7% as growth drivers, such as *Cosentyx* ($2.1 billion; +84%, +82% cc), *Entresto* ($507 million; +198%, +195% cc), *Promacta/Revolade* ($867 million; +37%, +37% cc), and *Tafinlar + Mekinist* ($873 million; +30%, +29% cc), more than offset the impact of patent expirations for *Gleevec/Glivec* ($1.9 billion; 42%, 41% cc).

The impact of currency exchange headwinds eased in 2017 compared to what we have seen for several years, particularly in 2015 when currency fluctuations had a negative 10% impact on sales. To help investors assess the impact of exchange rates on our performance, we continue to also indicate growth rates in constant currencies.

Operating income in 2017 was $8.6 billion (+4%, +7% cc), mainly driven by higher sales, productivity improvements and lower amortization, which were partly offset by generic competition and higher marketing investments to support product launches. Net income was $7.7 billion (+15%, +12% cc), benefiting from growth in operating income and higher income from our stake in GSK Consumer

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Healthcare Holdings Ltd.Earnings per share were $3.28 (+16%, +14% cc), benefiting from higher net income and our share buyback program.

Free cash flow rose 10% to $10.4 billion, driven mainly by improved cash flow from operating activities.

We also present our core results, which exclude the impact of amortization, impairments, disposals, acquisitions, restructurings and other significant items, to help investors understand our underlying performance.

Core operating income was $12.9 billion (1%, 0% cc). Core operating income margin in constant currencies decreased 0.3 percentage points, mainly due to generic competition for *Gleevec/Glivec*, and higher launch investments, which were partially offset by expanded gross margins and productivity improvements. Movements in exchange rates had an additional negative impact of 0.3 percentage points, yielding a net decrease of 0.6 percentage points to 26.2% of net sales.

Core net income was $11.4 billion (+1%, +2% cc), benefiting from higher core income from associated companies. Core earnings per share were $4.86 (+2%, +3% cc), reflecting the benefit of our share buyback program.

Our global functional organizations in manufacturing, quality and business services made progress in improving our operations. Novartis Technical Operations (NTO) and Novartis Business Services (NBS) continued to provide high-quality manufacturing and support services while making sustained productivity improvements through consolidation of our production network and suppliers, and process standardization. In 2017, these actions delivered productivity improvements of more than $0.3 billion across NTO and NBS. We remain on track to deliver our 2020 annual cost-savings goal of $1 billion, mainly driven by NTO.

In 2017, NTO completed its first full year as an integrated global manufacturing organization, delivering synergies across 67 pharmaceutical production facilities worldwide and improving capabilities through the sharing of skills and excellence across the manufacturing network.

Several new product launches in 2017 illustrated the benefits. For example, the launch of our new cancer drug *Kisqali* (ribociclib, formerly LEE011) involved contributions from team members from different technology platforms at several sites, as well as a joint effort from a global supply team supporting product launches. Close collaboration and joint program management helped us deliver products to patients and customers within six hours of approval from health authorities. That compares with four to six days in the best cases in past launches.

For recent launches including *Kisqali* and *Rydapt* (midostaurin) in the US, and the biosimilars *Erelzi* (etanercept) and *Rixathon* (rituximab) in the EU we were able to deliver products to patients and customers within 24 hours of approval. We aspire to that timing for future launches, as well.

We continued to perform well on quality, underscoring the success of our sustained focus on this area in recent years. Of 217 inspections of our facilities worldwide by health regulators in 2017, all but two or 99.1% were deemed acceptable, up from 98.1% the previous year. Additionally, in June we successfully closed out a warning letter from the US Food and Drug Administration (FDA) received by our site in Kalwe, India.

NBS continues to take steps to improve efficiency through such measures as simplifying and standardizing processes across the company, making the most of our global scale. Working with colleagues in our Global Drug Development (GDD) organization, for instance, NBS has upgraded our information technology platforms, streamlined hundreds of processes, and launched six new systems in 2017 with the aim of better equipping colleagues to focus on drug development activities. These include the planning, data management, statistical analysis, reporting, funding and management of clinical trials. These changes

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are expected to simplify work for more than 10,000 Novartis employees and facilitate more effective interactions with 145,000 external clinicians supporting our studies.

2017 Compared to 2016

Key figures

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales to third parties	**49,109**	**48,518**	**1**	**2**
Other revenues	1,026	918	12	11
Cost of goods sold	(17,175)	(17,520)	2	2
Gross profit	**32,960**	**31,916**	**3**	**4**
Marketing & Sales	(12,861)	(11,998)	(7)	(7)
Research & Development	(8,972)	(9,039)	1	1
General & Administration	(2,136)	(2,194)	3	2
Other income	1,969	1,927	2	1
Other expense	(2,331)	(2,344)	1	0
Operating income	**8,629**	**8,268**	**4**	**7**
Return on net sales (%)	17.6	17.0		
Income from associated companies	1,108	703	58	58
Interest expense	(777)	(707)	(10)	(12)
Other financial income and expense	39	(447)	nm	nm
Income before taxes	**8,999**	**7,817**	**15**	**12**
Taxes	(1,296)	(1,119)	(16)	(13)
Net income	**7,703**	**6,698**	**15**	**12**
Attributable to:				
Shareholders of Novartis AG	*7,703*	*6,712*	*15*	*12*
Non-controlling interests	*0*	*(14)*	*nm*	*nm*
Basic earnings per share ($)	**3.28**	**2.82**	**16**	**14**
Free cash flow	**10,428**	**9,455**	**10**	

nm = not meaningful

Group Overview

Novartis had solid performance in 2017 as strong sales of our growth drivers, including *Cosentyx* (secukinumab), *Entresto* (sacubitril/valsartan) and other recently launched products, continued to offset the impact of generic competition for our cancer treatment *Gleevec/Glivec*, which lost patent protection in the US and Europe during 2016. Our results underscore the breadth and strength of our product portfolio and highlight our success at steering through the patent expiration of one of our biggest-selling drugs.

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Promacta/Revolade ($867 million; +37%, +37% cc), and *Tafinlar + Mekinist* ($873 million; +30%, +29% cc), more than offset the impact of patent expirations for *Gleevec/Glivec* ($1.9 billion; 42%, 41% cc).

The impact of currency exchange headwinds eased in 2017 compared to what we have seen for several years, particularly in 2015 when currency fluctuations had a negative 10% impact on sales. To help investors assess the impact of exchange rates on our performance, we continue to also indicate growth rates in constant currencies.

Operating income in 2017 was $8.6 billion (+4%, +7% cc), mainly driven by higher sales, productivity improvements and lower amortization, which were partly offset by generic competition and higher marketing investments to support product launches. Net income was $7.7 billion (+15%, +12% cc), benefiting from growth in operating income and higher income from our stake in GSK Consumer Healthcare Holdings Ltd. Earnings per share were $3.28 (+16%, +14% cc), benefiting from higher net income and our share buyback program.

Free cash flow rose 10% to $10.4 billion, driven mainly by improved cash flow from operating activities.

Net Sales by Segment

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

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Innovative Medicines	**33,025**	**32,562**	**1**	**2**
Sandoz	**10,060**	**10,144**	**(1)**	**(2)**
Alcon	**6,024**	**5,812**	**4**	**4**
Net sales to third parties	**49,109**	**48,518**	**1**	**2**

Innovative Medicines

Innovative Medicines Division sales were $33.0 billion, up 1% in reported terms. In constant currencies (cc), sales grew 2%. An 8% increase in volume more than offset the impact of generic competition (5 percentage points) and price declines (1 percentage point). Products contributing to sales growth included *Cosentyx, Entresto, Promacta/Revolade, Tafinlar + Mekinist,* and *Jakavi.*

Regionally, sales performance was mixed. In the US, sales rose 2% (cc) to $11.1 billion, overcoming the impact of generic competition, mainly for *Gleevec*. Sales in Europe were $11.3 billion, in line with the prior year in constant currencies as growth drivers offset the impact of patent loss for *Gleevec/Glivec*. Sales rose 7% (cc) in emerging growth markets to $8.4 billion. Sales in Japan were $2.4 billion, in line with the prior year in constant currencies.

Novartis Oncology Business Unit

Oncology sales were $12.3 billion (4%, 3% cc), as strong performance of existing products and the launch of new products, including *Kisqali*, *Rydapt* and *Kymriah*, helped to partially offset the effects of generic competition on *Gleevec/Glivec* (42%, 41% cc). Significant gains on key hematology products such as *Tasigna* (1.8 billion; +6%, +9% cc), *Promacta/Revolade* ($867 million; +37%, +37% cc) and *Jakavi* ($777 million; +34%, +32% cc) were complemented by *Tafinlar + Mekinist* ($873 million; +30%, +29% cc), which was approved for advanced non-small cell lung cancer in addition to the existing use in melanoma.

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Novartis Pharmaceuticals Business Unit

Ophthalmology

Sales in the Ophthalmology franchise were $5.4 billion (2%, 1% cc), with increased sales of *Lucentis* (+3%, +4% cc) and *Systane* helping to partially offset the impact of generic competition.

Immunology and Dermatology

Sales in the Immunology and Dermatology franchise reached $4.0 billion (+34%, +35% cc). *Cosentyx* saw continued strong growth, particularly in the US and Europe, reaching $2.1 billion (+84%, +82% cc). *Ilaris* also continued strong gains (+42%, +42% cc), helping offset declines in other products mainly due to generic competition.

Neuroscience

Neuroscience franchise sales were $3.3 billion (+2%, +2% cc), driven by increases for *Gilenya* (+2%, +2% cc).

Respiratory

Respiratory franchise sales were $1.6 billion (+6%, +8% cc). Our chronic obstructive pulmonary disease (COPD) portfolio including *Onbrez Breezhaler*, *Seebri Breezhaler* and *Ultibro Breezhaler* achieved sales of $674 million (+3%, +5% cc). Sales of *Xolair,* for moderate-to-severe or severe persistent asthma, as well as for chronic hives, reached $920 million (+10%, +11% cc).

Cardio-Metabolic

Sales for the franchise were $524 million (+185%, +182% cc). *Entresto*, which has been launched in nearly 60 countries and used to treat more than 420,000 heart failure patients worldwide, continued to grow and sales reached $507 million (+198%, +195% cc).

Established Medicines

The Established Medicines franchise had sales of $5.9 billion (7%, 5% cc). Increased sales of *Galvus* ($1.2 billion; +3%, +5% cc) and *Exforge* ($960 million; +4%, +4% cc) were more than offset by declines for products such as *Diovan* ($957 million; 11%, 9% cc) and *Exelon/Exelon* Patch (14%, 14% cc) due to generic competition.

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TOP 20 INNOVATIVE MEDICINES DIVISION PRODUCT NET SALES 2017

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
Gilenya	Neuroscience	Relapsing multiple sclerosis	1,709	2	1,476	3	**3,185**	**2**	**2**
Cosentyx	Immunology and Dermatology	Psoriasis, ankylosing spondylitis and psoriatic arthritis	1,275	67	796	115	**2,071**	**84**	**82**
Gleevec/Glivec	Oncology	Chronic myeloid leukemia and GIST	627	(48)	1,316	(37)	**1,943**	**(42)**	**(41)**
Lucentis	Ophthalmology	Age-related macular degeneration			1,888	4	**1,888**	**3**	**4**
Tasigna	Oncology	Chronic myeloid leukemia	810	12	1,031	6	**1,841**	**6**	**9**
Sandostatin	Oncology	Carcinoid tumors and Acromegaly	832	(2)	780	1	**1,612**	**(2)**	**(1)**
Afinitor/Votubia	Oncology	Breast cancer / TSC	819	6	706	(3)	**1,525**	**1**	**2**
Galvus	Established Medicines	Diabetes			1,233	5	**1,233**	**3**	**5**
Exjade/Jadenu	Oncology	Chronic iron overload	515	15	544	8	**1,059**	**11**	**11**
Exforge	Established Medicines	Hypertension	28	180	932	2	**960**	**4**	**4**
Diovan/Co-Diovan	Established Medicines	Hypertension	87	(41)	870	(4)	**957**	**(11)**	**(9)**
Xolair [(1)]	Respiratory	Asthma			920	11	**920**	**10**	**11**
Tafinlar + Mekinist	Oncology	Melanoma	339	14	534	41	**873**	**30**	**29**
Promacta/Revolade	Oncology	Immune thrombocytopenic purpura	446	44	421	31	**867**	**37**	**37**
Votrient	Oncology	Renal cell carcinoma	407	14	401	7	**808**	**11**	**10**
Jakavi	Oncology	Myelofibrosis			777	32	**777**	**34**	**32**
Travoprost Group	Ophthalmology	Reduction of elevated intraocular pressure	216	2	373	(9)	**589**	**(5)**	**(5)**
Entresto	Cardio-Metabolic	Chronic Heart Failure	297	161	210	262	**507**	**198**	**195**
Neoral/Sandimmun(e)	Immunology and Dermatology	Transplantation	38	(7)	450	(4)	**488**	**(5)**	**(4)**
Voltaren/Cataflam	Established Medicines	Inflammation/pain			465	(4)	**465**	**(11)**	**(4)**
Top 20 products total			**8,445**	**6**	**16,123**	**3**	**24,568**	**4**	**4**
Rest of portfolio			2,671	(9)	5,786	0	**8,457**	**(4)**	**(3)**
Total Division sales			**11,116**	**2**	**21,909**	**2**	**33,025**	**1**	**2**

(1)

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

For information about the approved indications for the products described below, see "Item 4. Information on the Company Item 4.B Business Overview Innovative Medicines Key Marketed Products".

Gilenya ($3.2 billion, +2% cc) sales continued to grow across regions, mainly driven by volume.

Cosentyx ($2.1 billion, +82% cc) showed strong growth across all indications.

Gleevec/Glivec ($1.9 billion, 41% cc) continued to decline this year driven by generic competition primarily across Europe and the US.

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Lucentis ($1.9 billion, +4% cc) sales continued to grow driven by market expansion in Europe, Japan and Emerging Growth Markets, and reimbursement listing in China for neovascular age-related macular degeneration.

Tasigna ($1.8 billion, +9% cc) continued to grow this year primarily in the US and Emerging Growth Markets despite some impact of generic imatinib in Europe for patients with previously untreated Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia.

Sandostatin ($1.6 billion, 1% cc) declined slightly this year driven by increased competitive pressure primarily in the US and Japan partially offset by growth in Latin America and Emerging Growth Markets.

Afinitor/Votubia ($1.5 billion, +2% cc) grew slightly this year as the neuroendocrine tumors and tuberous sclerosis complex indications compensated for competitive pressure in the breast cancer and renal cell carcinoma indications.

Galvus Group ($1.2 billion, +5% cc) continues to grow driven by solid performance in Japan and Emerging Growth Markets.

Exjade/Jadenu ($1.1 billion, +11% cc) sales growth was primarily driven by solid growth in the US in addition to continued uptake of the film-coated tablet formulation in Europe.

Exforge Group ($960 million, +4% cc) grew despite ongoing generic competition in the US and Japan, and new generic competition in Europe in 2017. Growth was driven by Emerging Growth Markets.

Diovan Group ($957 million, 9% cc) saw sales decline due to loss of exclusivity including in the US, EU and Japan, while sales continued to grow in China and some Emerging Growth Markets.

Xolair ($920 million, +11% cc) sales showed balanced growth across all regions.

Tafinlar + Mekinist ($873 million, +29% cc) sales growth was primarily driven by combination uptake across Europe in addition to launch uptake in the US for the non-small cell lung cancer indication.

Promacta/Revolade ($867 million, +37% cc) continued to deliver solid double-digit growth across all regions.

Votrient ($808 million, +10% cc) worldwide growth was driven primarily by the advanced renal cell carcinoma indication both in the US and in Emerging Growth Markets, specifically China and Asia-Pacific countries.

Jakavi ($777 million, +32% cc) delivered strong double-digit growth across all regions driven by continued momentum in the myelofibrosis indication in addition to reimbursement and launch uptake in the polycythemia vera indication across Europe.

Travoprost Group ($589 million, 5% cc) sales declined mainly due to loss of exclusivity in Europe.

Entresto ($507 million, +195% cc) performance was driven by growing adoption by physicians in the US and EU, and continued market access improvement.

Neoral/Sandimmun(e) ($488 million, 4% cc) sales declined slightly due to generic competition and mandatory price reductions, mainly in Europe and Japan.

Voltaren/Cataflam ($465 million, 4% cc) sales were impacted by increased generic competition.

Sandoz

Sandoz net sales in 2017 were $10.1 billion, down 1% in reported terms. In constant currencies, or cc, sales declined 2%. A 6 percentage-point increase in volume was more than offset by the negative 8 percentage-point effect of price erosion. Sales rose 4% (cc) in Europe to $4.6 billion. In the US, where we continue to see customer consolidation and greater competition, sales were $3.3 billion (12% cc),

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mainly due to increased industry-wide pressure on prices in generics. Sales in Asia, Africa and Australasia were $1.4 billion, up 1% in constant currencies.

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Constant currencies change
	$ m	$ m	%	%
Retail Generics	8,409	8,623	(2)	(3)
Biopharmaceuticals	1,135	1,002	13	12
Anti-Infectives (Partner label/API)	516	519	(1)	(2)
Total	**10,060**	**10,144**	**(1)**	**(2)**

Retail Generics

Sandoz markets active ingredients, intermediates and finished dosage forms of pharmaceuticals. The Retail Generics franchise includes products in the therapeutic areas of cardiovascular, central nervous system, dermatology, gastrointestinal and hormonal therapies, metabolism, oncology, ophthalmics, pain and respiratory, plus finished dosage forms of anti-infectives sold under the Sandoz name. Franchise sales in 2017 were $8.4 billion (3% cc). Declines in the US (14% cc) more than offset increased sales in the rest of the world (+3% cc).

Biopharmaceuticals

The Biopharmaceuticals business comprises biosimilars; contract biologics supplied to third parties; and a generic version of Copaxone® 20 mg, *Glatopa*, which treats relapsing forms of multiple sclerosis and is marketed in the US. Global sales of Biopharmaceuticals grew 12% (cc) to $1.1 billion, driven by *Zarxio* (filgrastim), *Binocrit* (epoetin alfa), and the launch of *Rixathon* (rituximab) and *Erelzi* (etanercept) in several European countries.

Anti-Infectives

Sandoz sells pharmaceutical ingredients and intermediates (mainly antibiotics) to third-party customers, as well as finished dosage forms. Anti-infectives sold to third parties for sale under their own name were $516 million, down 2% (cc) due to the discontinuation of some low-margin products. Total Anti-Infectives sales were $1.4 billion, in line with the prior year in constant currencies, and included sales of finished dosage forms sold under the Sandoz name of $880 million, up 2% (cc).

Alcon

Alcon continued to implement its growth plan in 2017, with a focus on strengthening customer relationships, improving operations, and accelerating innovation and sales. In the US, Alcon launched the *AcrySof IQ ReSTOR* +2.5 D Multifocal Toric intraocular lens (IOL) with *ACTIVEFOCUS* optical design, which aims to improve distance vision in cataract patients with astigmatism. Other product launches in 2017 include the *CyPass* Micro-Stent in the EU to treat glaucoma. Alcon also received European approval for the *Clareon* IOL with *AutonoMe* pre-loaded delivery system, the first and only automated, disposable IOL delivery system for cataract surgery.

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	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Constant currencies change
	$ m	$ m	%	%
Surgical				
Cataract products	2,749	2,695	2	3
of which Consumables	*1,443*	*1,390*	*4*	*5*
IOLs	*995*	*986*	*1*	*3*
Equipment	*311*	*319*	*(3)*	*(2)*
Vitreoretinal products	686	616	11	11
Refractive/other	225	207	9	8
Total	**3,660**	**3,518**	**4**	**5**
Vision Care				
Contact lenses	1,833	1,762	4	4
Contact lens care	531	532	0	0
Total	**2,364**	**2,294**	**3**	**3**
Total net sales	**6,024**	**5,812**	**4**	**4**

Surgical

Surgical sales grew 5% (cc) to $3.7 billion, mainly due to strong performance of products in the vitreoretinal portfolio (+11% cc) and growth in cataract disposable surgical supplies (+5% cc). Intraocular lenses for cataract surgery grew 3% (cc), as strong performance of new products including the *UltraSert* pre-loaded IOL delivery device, the *PanOptix* trifocal IOL, and *AcrySof ReSTOR* Toric IOL with *ACTIVEFOCUS* optical design was partly offset by competitive pressures.

Vision Care

Vision Care sales grew 3% (cc) to $2.4 billion. Contact lens sales grew 4% (cc) on the back of continued double-digit growth of *Dailies Total1*, the world's first and only water-gradient lens. Sales of contact lens care products were in line with the prior year in constant currencies.

Operating Income

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

	Year ended Dec 31, 2017	% of net sales	Year ended Dec 31, 2016	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Innovative Medicines	**7,782**	**23.6**	**7,426**	**22.8**	**5**	**7**
Sandoz	**1,368**	**13.6**	**1,445**	**14.2**	**(5)**	**(7)**
Alcon	**(190)**	**(3.2)**	**(132)**	**(2.3)**	**(44)**	**(14)**
Corporate	(331)		(471)		30	27
Operating income	**8,629**	**17.6**	**8,268**	**17.0**	**4**	**7**

Operating income was $8.6 billion (+4%, +7% cc) as growth drivers, productivity, lower amortization and a gain from achievement of a sales milestone related to the 2015 Vaccines divestment to GSK more than offset generic erosion. Operating income margin in constant currencies increased 0.8 percentage points compared to the prior year; currency had a negative impact of 0.2 percentage points resulting in an increase of 0.6 percentage points to 17.6% of net sales.

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Core Operating Income key figures[1]

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core gross profit	**36,578**	**35,806**	**2**	**3**
Core Marketing & Sales	(12,865)	(11,991)	(7)	(7)
Core Research & Development	(8,313)	(8,402)	1	1
Core General & Administration	(2,135)	(2,120)	(1)	(2)
Core other income	778	753	3	2
Core other expense	(1,193)	(1,059)	(13)	(13)
Core operating income	**12,850**	**12,987**	**(1)**	**0**
As % of net sales	26.2	26.8		

(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 amounted to $4.2 billion (2016: $4.7 billion), less than in the prior year due to lower amortization and a gain from achievement of a sales milestone related to the 2015 Vaccines divestment to GSK.

Excluding these items, Core operating income was $12.9 billion (1%, 0% cc). Core operating income margin in constant currencies decreased 0.3 percentage points, mainly due to generic competition for *Gleevec/Glivec*, and higher launch investments, which were partially offset by expanded gross margin and productivity improvements. Currency exchange rates had an additional negative impact of 0.3 percentage points, yielding a net decrease of 0.6 percentage points to 26.2% of net sales.

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

	Year ended Dec 31, 2017	% of net sales	Year ended Dec 31, 2016	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Innovative Medicines	**10,330**	**31.3**	**10,354**	**31.8**	**0**	**2**
Sandoz	**2,080**	**20.7**	**2,071**	**20.4**	**0**	**(1)**
Alcon	**857**	**14.2**	**850**	**14.6**	**1**	**5**
Corporate	(417)		(288)		(45)	(53)
Core operating income	**12,850**	**26.2**	**12,987**	**26.8**	**(1)**	**0**

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

Innovative Medicines

Operating income was $7.8 billion (+5%, +7% cc), mainly driven by higher sales, productivity improvements and lower amortization, which offset the impact of generic competition and investments in growth drivers.

Core operating income, which excludes certain items, was $10.3 billion (0%, +2% cc). Core operating income margin decreased 0.1 percentage points in constant currencies, and fluctuations in exchange rates had a further negative impact of 0.4 percentage points, resulting in a net decrease of 0.5 percentage points to 31.3% of net sales.

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Research and development of Innovative Medicines Division

The following table provides an overview of the reported and core research and development expense of the Innovative Medicines Division:

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Research and Exploratory Development[1]	(2,749)	(2,739)	0	0
Confirmatory Development[1]	(4,881)	(4,970)	2	2
Total Innovative Medicines Division Research and Development expense	**(7,630)**	**(7,709)**	**1**	**1**
As % of Innovative Medicines net sales to third parties	*23.1*	*23.7*		
Core Research and Exploratory Development[1],[2]	(2,623)	(2,637)	1	1
Core Confirmatory Development[1],[2]	(4,426)	(4,475)	1	1
Total Core Innovative Medicines Division Research and Development expense	**(7,049)**	**(7,112)**	**1**	**1**
As % of Innovative Medicines net sales to third parties	*21.3*	*21.8*		

(1) Certain prior year amounts have been reclassified for comparative purposes. This reclassification has not been made in the 2015-2016 comparative table found in " 2016 Compared to 2015 Innovative Medicines Research and development of Innovative Medicines Division".

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

Innovative Medicines Division Research and Exploratory Development expense amounted to $2.7 billion in 2017, in line with the prior year. Confirmatory Development expense decreased by 2% (+2% cc) to $4.9 billion compared to $5.0 billion in 2016, driven by resource allocation and continued productivity efforts, including the benefit of the creation of the Novartis Global Drug Development (GDD) organization.

Total Core Research and Development expense in the Innovative Medicines Division as a percentage of sales decreased by 0.7 percentage points in constant currencies mainly due to resource allocation and continued productivity efforts. Currency exchange rates had a negative impact of 0.2 percentage points, yielding a net decrease of 0.5 percentage points to 21.3% of net sales.

Sandoz

Operating income was $1.4 billion (5%, 7% cc), down mainly due to pressure on prices in the US, investments in marketing and sales in key markets outside the US, and higher manufacturing restructuring charges. These negative impacts were partly offset by favorable changes in product mix.

Core operating income, which excludes certain items, was $2.1 billion (0%, 1% cc). Core operating income margin in constant currencies increased 0.1 percentage points, and an additional 0.2 percentage-point increase from exchange rates yielded a result of 20.7% of net sales.

Alcon

Operating loss was $190 million, compared to an operating loss of $132 million the year before, as higher sales were offset by continued investment in the division's growth plan and charges related to business development activities.

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Core operating income, which excludes certain items, was $857 million (+1%, +5% cc). Core operating income margin in constant currencies increased by 0.2 percentage points, offset by negative currency impact of 0.6 percentage points, yielding a net decrease of 0.4 percentage points to 14.2% of net sales.

Corporate Income and Expense, Net

Corporate income and expense, which includes the cost of Group management and central services, amounted to a net expense of $331 million (+30%, +27% cc) in 2017 compared to a net expense of $471 million in the prior year. The favorable decrease in expense was mainly due to a gain from achievement of a sales milestone related to the 2015 Vaccines divestment to GSK, partly offset by lower gains from divestment in real estate and lower contributions from the captive insurance companies.

Non-Operating Income and Expense

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

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Operating income	**8,629**	**8,268**	**4**	**7**
Income from associated companies	1,108	703	58	58
Interest expense	(777)	(707)	(10)	(12)
Other financial income and expense	39	(447)	nm	nm
Income before taxes	**8,999**	**7,817**	**15**	**12**
Taxes	(1,296)	(1,119)	(16)	(13)
Net income	**7,703**	**6,698**	**15**	**12**
Basic EPS ($)	**3.28**	**2.82**	**16**	**14**

nm = not meaningful

Income from associated companies

Income from associated companies increased to $1.1 billion, compared to $703 million in the prior year. The increase was due to higher income recognized from our investment in GSK Consumer Health-care Holdings Ltd. (GSK Consumer Healthcare).

The estimated income from our investment in GSK Consumer Healthcare in 2017 amounted to $629 million compared to $234 million in 2016. The increase is due to improved operational results of $89 million, an estimate of a one-time deferred tax income of $237 million, arising from a change in a Swiss cantonal statutory tax rate, and a positive prior year adjustment of $47 million based on the actual audited results for 2016, compared to a negative prior year adjustment of $22 million recognized in 2016 for 2015.

The estimated income from our investment in Roche in 2017 amounted to $456 million (2016: $464 million), which reflected our estimated share of income for 2017 of $523 million (2016: $532 million) offset by the negative prior year adjustment of $67 million, based on actual 2016 results (2016: negative prior year adjustment of $68 million, based on actual 2015 results).

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Interest Expense and other financial income and expense

Interest expense increased to $777 million from $707 million in the prior year due to higher outstanding debt.

Other financial income and expense amounted to an income of $39 million compared to an expense of $447 million in the prior-year, mainly on account of exceptional charges related to Venezuela of $305 million in 2016, as well as higher currency losses in 2016.

Taxes

The tax rate increased to 14.4% from 14.3% in the prior year. On December 22, 2017, the US enacted tax reform legislation (Tax Cuts and Jobs Act), which among other provisions, reduced the US corporate tax rate from 35% to 21%, effective January 1, 2018. This required a revaluation of the deferred tax assets and liabilities and a portion of current tax payables to the newly enacted tax rate at the date of enactment, which resulted in a net tax expense of $61 million (0.7%). In addition, a change in a Swiss cantonal statutory tax rate resulted in a one-time income from our share in GSK Consumer Healthcare the impact of which decreased the tax rate by 0.4%.

Excluding the impact of these rate changes the reported tax rate for 2017 would have been 14.1% compared to 14.3% in the prior year.

Net Income

Net income was $7.7 billion (+15%, +12% cc), benefiting from growth in operating income and higher income from our stake in GSK Consumer Healthcare Holdings Ltd. The prior year also included the exceptional charges related to Venezuela.

EPS

Basic earnings per share were $3.28 (+16%, +14% cc), up more than net income in constant currencies, benefiting from our share buyback program.

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

Core Non-Operating Income and Expense

	Year ended Dec 31, 2017	Year ended Dec 31, 2016	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core operating income	**12,850**	**12,987**	**(1)**	**0**
Core income from associated companies	1,335	1,134	18	18
Core interest expense	(777)	(707)	(10)	(12)
Core other financial income and expense	39	(99)	nm	nm
Core income before taxes	**13,447**	**13,315**	**1**	**2**
Core taxes	(2,056)	(2,001)	(3)	(4)
Core net income	**11,391**	**11,314**	**1**	**2**
Core basic EPS ($)	**4.86**	**4.75**	**2**	**3**

nm = not meaningful

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Core Income from associated companies

Core income from associated companies increased to $1.3 billion from $1.1 billion in the prior-year period. The core income contribution from GSK Consumer Healthcare Holdings Ltd., increased to $479 million in 2017 from $369 million in the prior-year period, and the core income contribution from Roche increased to $832 million from $760 million.

Core Interest Expense and other financial income and expense

Core other financial income and expense amounted to a net income of $39 million, compared to an expense of $99 million in 2016, mainly on account of lower currency losses. In the prior year, the exceptional charges of $0.3 billion related to Venezuela were excluded from the 2016 core other financial expense.

Core Taxes

The core tax rate (core taxes as a percentage of core pre-tax income) increased to 15.3% from 15.0% in the prior year.

Core Net Income

Core net income was $11.4 billion (+1%, +2% cc), benefiting from higher core income from associated companies.

Core EPS

Core earnings per share were $4.86 (+2%, +3% cc), reflecting the benefit of our share buyback program.

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2016 Compared to 2015

Key figures

	Year ended Dec 31, 2016	Year ended Dec 31, 2015	Change in $	Change in constant currencies
	$ m	$ m	%	%
Net sales to third parties from continuing operations	**48,518**	**49,414**	**(2)**	**0**
Sales to discontinued operations		26	nm	nm
Net sales from continuing operations	**48,518**	**49,440**	**(2)**	**0**
Other revenues	918	947	(3)	(3)
Cost of goods sold	(17,520)	(17,404)	(1)	(2)
Gross profit from continuing operations	**31,916**	**32,983**	**(3)**	**(1)**
Marketing & Sales	(11,998)	(11,772)	(2)	(4)
Research & Development	(9,039)	(8,935)	(1)	(2)
General & Administration	(2,194)	(2,475)	11	8
Other income	1,927	2,049	(6)	(5)
Other expense	(2,344)	(2,873)	18	17
Operating income from continuing operations	**8,268**	**8,977**	**(8)**	**(3)**
Return on net sales (%)	17.0	18.2		
Income from associated companies	703	266	164	164
Interest expense	(707)	(655)	(8)	(10)
Other financial income and expense	(447)	(454)	2	58
Income before taxes from continuing operations	**7,817**	**8,134**	**(4)**	**2**
Taxes	(1,119)	(1,106)	(1)	(13)
Net income from continuing operations	**6,698**	**7,028**	**(5)**	**1**
Net income from discontinued operations		10,766	nm	nm
Net income	**6,698**	**17,794**	**(62)**	**(59)**
Attributable to:				
Shareholders of Novartis AG	*6,712*	*17,783*	*(62)*	*(59)*
Non-controlling interests	*(14)*	*11*	*nm*	*nm*
Basic earnings per share ($) from continuing operations	**2.82**	**2.92**	**(3)**	**2**
Basic earnings per share ($) from discontinued operations		4.48	nm	nm
Total basic earnings per share ($)	**2.82**	**7.40**	**(62)**	**(59)**
Free cash flow from continuing operations	**9,455**	**9,259**	**2**	
Free cash flow	**9,455**	**9,029**	**5**	

nm = not meaningful

Group overview

Novartis delivered solid results in 2016, countering much of the effects of the loss of US patent protection during the year for our pioneering leukemia drug, *Gleevec*. This underscores the strength of our pipeline and our ability in recent years to renew our product portfolio and control costs to manage through important patent expirations. *Gleevec* follows *Diovan*, which lost exclusivity in 2011 in the EU and in 2012 in the US.

Our Innovative Medicines and Sandoz Divisions performed well under challenging circumstances. We were not successful in returning Alcon to growth in 2016, although we have begun to see the first results from the growth plan implemented during the year.

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Net sales for Novartis in 2016 were $48.5 billion, down 2% in reported terms, but flat measured in constant currencies (cc) to remove the impact of fluctuations in exchange rates. While volumes grew 6 percentage points, that was offset by the negative impacts of 4 percentage points due to generic competition and 2 percentage points from lower prices.

We continued to face headwinds in 2016 from currency fluctuations, with the rising value of the dollar adversely affecting our reported sales and income. This continues a trend we have seen for several years, particularly in 2015 when currency fluctuations had a negative 10% impact on sales. To help investors assess the impact of exchange rates on our performance, we also indicate growth rates in constant currencies.

In 2016, our growth products[1] contributed $17.1 billion, or 35% of net sales. These include *Gilenya* for multiple sclerosis, up 14% (cc) to $3.1 billion; *Cosentyx* for psoriasis and two other immune-related illnesses, which reached blockbuster status with sales of $1.1 billion; *Jakavi* for blood cancer, up 45% to $581 million; and the combination cancer therapy *Tafinlar + Mekinist*, acquired from GSK during 2015 ($672 million).

Biopharmaceutical products from Sandoz also continued to be a bright spot, rising 31% (cc) to $1.0 billion.

Sales of heart failure drug *Entresto* grew steadily during the year and totaled $170 million. We continued to increase our investment in its launch, devoting additional resources during the year to educating doctors and patients about its benefits.

Operating income in 2016 was $8.3 billion (8%, 3% cc), down mainly due to the effects of patent expirations and increased investments related to new product launches, including *Entresto* and *Cosentyx*, and the Alcon growth plan.

Net income from continuing operations was $6.7 billion, down 5% in reported terms, but up 1% in constant currencies, due to higher income from associated companies.

Basic earnings per share from continuing operations were $2.82 (3%, +2% cc), up more than net income due to a reduction in the average number of shares outstanding.

Free cash flow from continuing operations was $9.5 billion, up 2%, reflecting lower net investment in property, plant and equipment.

For the total Group, net income amounted to $6.7 billion in 2016 compared to $17.8 billion in 2015. The prior year benefitted from the $10.8 billion net income from discontinued operations, which included $12.7 billion of exceptional pre-tax divestment gains and the operational results of the divested businesses until the respective dates of completion of the transactions. For more information on discontinued operations, see " Factors Affecting Comparability of Year-on Year Results of Operations" below and "Note 29. Discontinued operations" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Basic earnings per share decreased to $2.82 from $7.40 in the prior year.

Free cash flow for the total Group amounted to $9.5 billion in 2016 compared to $9.0 billion in 2015. The prior year included a negative free cash flow of approximately $0.3 billion from discontinued operations.

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[1] "Growth products" are an indicator of the rejuvenation of the portfolio, and comprise products launched in a key market (EU, US, Japan) in 2011 or later, or products with exclusivity in key markets until at least 2020 (except Sandoz, which includes only products launched in the last 24 months). They include the acquisition effect of the GSK oncology assets.

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Productivity

Efforts to improve productivity are delivering results. Novartis Business Services (NBS), our shared services organization, continued to leverage the global scale of Novartis to streamline and consolidate our operations. For example, we reduced the number of information technology applications we use, consolidated facilities services from more than 100 suppliers to just three, and initiated the standardization of infrastructure services at selected manufacturing sites, among other steps. In addition, NBS continued to optimize its footprint through selective offshoring to five global service centers.

NBS, as well as our newly created Global Drug Development (GDD) organization and global Novartis Technical Operations (NTO) group, will continue to drive the pursuit of greater efficiency and effectiveness. We anticipate that the benefits of the new GDD and NTO organizations will yield more than $1 billion in annual cost savings by 2020.

Net Sales by Segment

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

	Year ended Dec 31, 2016	Year ended Dec 31, 2015	Change in $	Change in constant currencies
	$ m	$ m	%	%
Innovative Medicines[1][2]	**32,562**	**33,345**	**(2)**	**0**
Sandoz[2]	**10,144**	**10,070**	**1**	**2**
Alcon[2]	**5,812**	**5,999**	**(3)**	**(2)**
Net sales to third parties from continuing operations	**48,518**	**49,414**	**(2)**	**0**

(1) Formerly named the Pharmaceuticals Division

(2) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

Innovative Medicines

Innovative Medicines Division sales were $32.6 billion, down 2% in reported terms, but in line with the prior year in constant currencies (cc). A 7% increase in volume was offset by the impact of generic competition (6 percentage points) and price declines (1 percentage point).

Sales performance varied by geography. Sales in Europe were $11.2 billion, up 7% in constant currencies, and reached $8.1 billion in emerging growth markets, up 6% (cc). In the US, sales declined 8% (cc) to $10.9 billion, mainly due to generic competition for *Gleevec* following loss of patent protection there in February. And in Japan, sales declined 10% (cc), due to generic competition and divestments.

Growth products contributed $14.8 billion, up 24% in constant currencies. These products which include *Gilenya*, *Cosentyx*, *Entresto*, *Tasigna*, *Jakavi*, and the combination of *Tafinlar + Mekinist* represented 45% of net sales, compared to 37% in 2015.

Novartis Pharmaceuticals Business Unit

Ophthalmology

Sales in Ophthalmology were $5.5 billion (8%, 6% cc), primarily reflecting declines in *Lucentis* (11%, 8% cc), which continues to see increasing competitive pressure in Japan and some European countries.

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Neuroscience

Neuroscience sales were $3.7 billion (+1%, +2% cc), with increases for *Gilenya* (+12%, +14% cc) being offset by lower sales of *Exelon* and *Exelon* Patch (39%, 39% cc), due to generic competition for *Exelon* Patch in the US and EU.

Immunology and Dermatology

Sales in Immunology and Dermatology reached $3.0 billion (+41%, +44% cc). Sales of *Cosentyx* continued to accelerate, reaching $1.1 billion, versus $261 million in 2015. Gains for *Ilaris* (+20%, +22% cc) also helped offset declines in other products due to generic competition.

Respiratory

Respiratory sales were $1.5 billion (+11%, +15% cc). Our portfolio of drugs for chronic obstructive pulmonary disease (COPD) including *Onbrez Breezhaler/Arcapta Neohaler*, *Seebri Breezhaler* and *Ultibro Breezhaler* achieved sales of $655 million (+14%, +16% cc). Sales of *Xolair,* the first biologic drug approved for moderate-to-severe allergic asthma, reached $835 million (+11%, +15% cc), including as a treatment for chronic hives.

Cardio-Metabolic

Sales for the franchise were $1.4 billion (+19%, +20% cc). *Entresto* which has been launched in more than 30 countries and benefited from a strong endorsement in updated clinical practice guidelines in the US and EU continued to grow steadily and sales reached $170 million, up from $21 million in 2015. *Galvus* sales were $1.2 billion (+5%, +6% cc).

Established Medicines

Established medicines such as *Diovan* ($1.1 billion, 13% cc) and *Exforge* ($926 million, 8% cc) continued to see declines due to generic competition.

Novartis Oncology business unit

Oncology sales were $12.8 billion (4%, 2% cc), nearly even with the prior year, despite declining sales of *Gleevec/Glivec* (29%, 28% cc) due to generic competition in the US. That decline was largely offset by growth in other products. Products showing growth included the combination therapy *Tafinlar + Mekinist* ($672 million); *Votrient* ($729 million); *Promacta/Revolade* ($635 million); and *Jakavi*, up 45% (cc) to $581 million.

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TOP 20 INNOVATIVE MEDICINES DIVISION[1] PRODUCT NET SALES 2016

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	1,214	(52)	2,109	1	**3,323**	**(29)**	**(28)**
Gilenya	Neuroscience	Relapsing multiple sclerosis	1,683	12	1,426	15	**3,109**	**12**	**14**
Lucentis	Ophthalmology	Age-related macular degeneration			1,835	(8)	**1,835**	**(11)**	**(8)**
Tasigna	Oncology	Chronic myeloid leukemia	722	9	1,017	10	**1,739**	**7**	**10**
Sandostatin	Oncology	Carcinoid tumors and Acromegaly	853	4	793	3	**1,646**	**1**	**3**
Afinitor/Votubia	Oncology	Breast cancer / TSC	775	(13)	741	6	**1,516**	**(6)**	**(5)**
Galvus	Cardio-Metabolic	Diabetes			1,193	6	**1,193**	**5**	**6**
Cosentyx	Immunology and Dermatology	Psoriasis, ankylosing spondylitis and psoriatic arthritis	765	nm	363	nm	**1,128**	**nm**	**nm**
Diovan/Co-Diovan	Established Medicines	Hypertension	147	(42)	926	(6)	**1,073**	**(16)**	**(13)**
Exjade/Jadenu	Oncology	Chronic iron overload	447	22	509	(6)	**956**	**4**	**6**
Exforge	Established Medicines	Hypertension	10	(85)	916	(3)	**926**	**(12)**	**(8)**
Xolair[2]	Respiratory	Asthma			835	15	**835**	**11**	**15**
Votrient	Oncology	Renal cell carcinoma	357	nm	372	nm	**729**	**nm**	**nm**
Tafinlar/Mekinist	Oncology	Melanoma	298	nm	374	nm	**672**	**nm**	**nm**
Promacta/Revolade	Oncology	Immune thrombocytopenic purpura	310	nm	325	nm	**635**	**nm**	**nm**
Travoprost Group	Ophthalmology	Reduction of elevated intraocular pressure	211	6	408	(5)	**619**	**(2)**	**(1)**
Jakavi	Oncology	Myelofibrosis			581	45	**581**	**42**	**45**
Voltaren/Cataflam	Established Medicines	Inflammation/pain			525	1	**525**	**(6)**	**1**
Neoral/Sandimmun(e)	Immunology and Dermatology	Transplantation	41	(13)	474	(9)	**515**	**(10)**	**(9)**
Exelon/Exelon **Patch**	Neuroscience	Alzheimer's disease	90	(74)	354	(8)	**444**	**(39)**	**(39)**
Top 20 products total			**7,923**	**(8)**	**16,076**	**7**	**23,999**	**0**	**2**
Rest of portfolio			2,974	(7)	5,589	(4)	**8,563**	**(8)**	**(5)**
Total Division sales			**10,897**	**(8)**	**21,665**	**4**	**32,562**	**(2)**	**0**

(1) Formerly named the Pharmaceuticals Division.

(2)

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

nm = not meaningful

Gleevec/Glivec ($3.3 billion, 28% cc) is a kinase inhibitor approved as a targeted therapy for Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) and 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. First launched in 2001, *Gleevec/Glivec* is approved in more than 110 countries. *Gleevec/Glivec* is also approved in the US, EU and Japan to treat Ph+ acute lymphoblastic leukemia, a rapidly progressive form of leukemia. In addition, *Gleevec/Glivec* is approved in the US and EU to treat dermatofibrosarcoma protuberans, a rare solid

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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 80 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.

Gilenya ($3.1 billion, +14% cc) 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* impacts four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. Its effectiveness on all of these measures has been consistently shown in multiple controlled clinical studies and in the real-world setting. As of November 2016, more than 180,000 patients have been treated in clinical trials and in a post-marketing setting, with more than 395,000 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.

Lucentis ($1.8 billion, 8% cc) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factor A (VEGF-A), a key mediator of intraocular neovascularization. Approved in 2006 as the first anti-VEGF for ocular use Lucentis revolutionized the therapy for patients with neovascular age related macular degeneration (nAMD). Today Lucentis is licensed for six ocular indications: 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), visual impairment due to choroidal neovascularization secondary to pathologic myopia (myopic CNV) and visual impairment due to choroidal neovascularization secondary to other pathologies. Approval of the sixth indication was received in Europe in November 2016, and submissions have been filed in 22 other countries, including Switzerland, Australia, Indonesia and Brazil. Lucentis is the only treatment available for a wide range of CNV conditions confirming it in diseases of the retina. The label of *Lucentis* was updated in September 2014 allowing flexible treatment (including a treat and extent regimen) already in the first year of therapy. In April 2016 the label of *Lucentis* was further updated to include the treatment of RVO patients with retinal ischemia. In November 2016, the EMA approved *Lucentis* to treat patients with visual impairment due to choroidal neovascularization (CNV) associated with causes other than neovascular age-related macular degeneration or myopic CNV. *Lucentis* is the only anti-VEGF treatment available in a pre-filled syringe and approved for a treat and extend regimen in the first year of therapy. Since its launch in 2007, there have been more than 4.3 million patient-treatment years of exposure for *Lucentis* and more than 26.8 million injections. Novartis licensed *Lucentis* from Genentech for development and commercialization outside of the US.

Tasigna ($1.7 billion, +10% cc) is a signal transduction inhibitor of the BCR-ABL tyrosine kinase. Since its launch in 2007, *Tasigna* has been approved in more than 125 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 120 markets, including the US, EU member states, Switzerland and Japan, to treat newly diagnosed patients in the chronic phase.

Sandostatin ($1.6 billion, +3% cc) 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

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neuroendocrine tumors of the midgut or unknown primary tumor location. *Sandostatin* was first launched in 1988 and is approved in more than 100 countries.

Afinitor/Votubia ($1.5 billion, 5% cc) 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 patients with 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 110 countries, including the US, EU member states and Japan for the treatment of locally advanced, metastatic or unresectable progressive neuroendocrine tumors (NET) of pancreatic origin. Afinitor was approved in the US in February and the EU in June for the treatment of patients with progressive, well-differentiated, nonfunctional NET of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic, and is approved for this indication in more than 40 countries worldwide. In addition, *Afinitor* is approved in more than 110 countries for hormone receptor-positive advanced breast cancer in combination with an aromatase inhibitor, after prior endocrine therapy. Everolimus, under the trade name *Afinitor* in the US and *Votubia* in the EU, is also approved in more than 95 countries to treat patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma not requiring immediate surgery, and in more than 90 countries to treat patients with TSC who have renal angiomyolipoma not requiring immediate surgery. A dispersible tablet for oral suspension formulation is approved for patients with TSC who have SEGA in more than 40 countries including the US (under the trade name *Afinitor Disperz*), EU member states (under the trade name *Votubia*) and Japan (under the trade name *Afinitor*). 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.

Galvus Group ($1.2 billion, +6% 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. 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 approval was for the use of vildagliptin in combination with insulin, with or without metformin, for patients with type 2 diabetes when diet, exercise and a stable dose of insulin do not result in glycemic control. The second approval was for the use of vildagliptin in triple combination with metformin and a sulphonylurea for the treatment of type 2 diabetes when diet and exercise plus dual therapy with these two agents do not provide adequate glycemic control. *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.

Cosentyx ($1.1 billion) is a fully human monoclonal antibody that selectively neutralizes circulating interleukin 17A (IL-17A). *Cosentyx* has been approved in over 75 markets, including the US and countries of the EU, for the treatment of moderate-to-severe plaque psoriasis. *Cosentyx* is also 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 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. *Cosentyx* is approved in more than 65 countries for the treatment of adults with ankylosing spondylitis and psoriatic arthritis, including the US, countries of the EU, Canada and Australia. *Cosentyx* is approved in Japan for the treatment of moderate-to-severe plaque psoriasis, pustular psoriasis, and both psoriasis vulgaris and psoriatic arthritis in adults who are not adequately responding to systemic therapies (except for biologics).

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Diovan Group ($1.1 billion, 13% cc), consisting of *Diovan* monotherapy and the combination product *Co-Diovan/Diovan* HCT, is an angiotensin II receptor blocker (ARB). *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.

Exjade/Jadenu ($956 million, +6% cc), is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older, as well as chronic iron overload in patients with non-transfusion dependent thalassemia in patients 10 years of age and older. 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*, a dispersible tablet for oral suspension, was first approved in 2005 and is now approved in more than 100 countries, including the US, EU member states and Japan. An oral film-coated tablet formulation that can be swallowed or crushed is approved in the US and Canada under the tradename *Jadenu*. It was approved by EMA in 2016 under the tradename of *Exjade*. Regulatory applications have been submitted in Switzerland and other countries. In addition to the film-coated tablet formulation, a new formulation has also been developed as granules for patients who cannot swallow tablets, using the same composition as the film-coated tablet formulations. Regulatory applications for granules formulation have been submitted under the name *Jadenu* in the US and Japan and under the name *Exjade* in the EU.

Exforge Group ($926 million, 8% 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) three widely prescribed blood pressure treatments. First approved for the treatment of high blood pressure in Switzerland in 2006, and in the US and EU in 2007, *Exforge* is now available in more than 100 countries. *Exforge* HCT was approved in the EU and the US in 2009, and is now available in more than 75 countries.

Xolair ($835 million, +15% cc) is a recombinant, DNA-derived, humanized IgG1K monoclonal antibody. *Xolair* is designed to block IgE, which limits the release of mediators in the early and late phases of the allergic inflammatory cascade. *Xolair* is approved for the treatment of moderate-to-severe, or severe, persistent allergic asthma in more than 90 countries, including the US since 2003, the EU since 2005, and Japan since 2009. *Xolair* is provided as lyophilized powder for resolution, and in addition as liquid formulation in a pre-filled syringe in most European countries. *Xolair* is currently approved in the EU, Switzerland and more than 80 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. 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.

Votrient ($729 million) 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 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

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soft tissues including muscle, fat, blood vessel and nerves. *Votrient* is approved in more than 100 countries worldwide for aRCC and in more than 90 countries for aSTS. *Votrient* was acquired from GSK.

Tafinlar + *Mekinist* ($672 million) 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. *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 a BRAF and a MEK inhibitor to demonstrate an overall survival benefit over BRAF inhibitor monotherapy after three 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 60 and 40 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., to develop, manufacture, and commercialize trametinib.

Promacta/Revolade ($635 million) is a once-daily oral thrombopoietin 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. It is approved in more than 100 countries for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an inadequate response or are intolerant to other treatments. In the US and EU, *Promacta/Revolade* is approved for patients one year and older with chronic ITP who have had an inadequate response to other treatments. *Promacta/Revolade* may be considered as second line treatment for adult non-splenectomised patients where surgery is contraindicated. *Promacta/Revolade* is also approved in 45 countries for the treatment of patients with severe aplastic anemia (SAA) who are refractory to other treatments (in the US for the treatment of patients with SAA who have had an insufficient response to immunosuppressive therapy and in the EU 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). In addition, *Promacta/Revolade* is approved in more than 50 countries for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow them to initiate and maintain interferon-based therapy. *Promacta/Revolade* is marketed under a collaboration agreement between Ligand Pharmaceuticals, Inc., and Novartis. *Promacta/Revolade* was acquired from GSK.

Travoprost Group ($619 million, 1% cc), including *Travatan, Travatan Z*, and *Duotrav*, are indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or who have ocular hypertension. Single agent travoprost products (*Travatan, Travatan Z, Travatan* BAK-Free and *Izba*) are prescribed as first-line agents and are marketed in more than 140 countries, including the US, countries of the EU, Canada and China. *Duotrav* is a fixed-dose combination solution of the prostaglandin analogue travoprost with the beta-blocker timolol, and is approved as a second-line treatment in adults for the reduction of IOP in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. *Duotrav* is currently marketed in more than 140 countries, including countries of the EU, Canada and China.

Jakavi ($581 million, +45% cc) 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 100 countries for patients with myelofibrosis and in more than 65 countries for patients with polycythemia vera, including EU member states and Japan. A five year follow-up of the two pivotal trials, COMFORT-I and COMFORT-II suggests an overall survival advantage for patients randomized to *Jakavi* compared to placebo or best available therapy, respectively. Novartis licensed ruxolitinib from Incyte Corporation for development and

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commercialization in the indications of oncology, hematology and Graft-versus-host disease 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.

Voltaren/Cataflam ($525 million, +1% 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 is marketed by the Innovative Medicines Division in a wide variety of dosage forms including tablets, drops, suppositories, ampoules and topical therapy. Our Sandoz Division also markets generic versions of the product in various countries. 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.

Neoral/Sandimmun(e) ($515 million, 9% cc) 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.

Exelon/Exelon Patch ($444 million, 39% cc) are cholinesterase inhibitors indicated for the treatment of Alzheimer's disease (AD) dementia and Parkinson's disease (PD) dementia. They are the oral and transdermal formulations, respectively, of the cholinesterase inhibitor rivastigmine. *Exelon* capsules have been available since 1997 to treat mild to moderate AD dementia and are approved in more than 85 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 85 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. The once-daily formulation *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. The severe indication has now been approved in more than 10 countries.

Sandoz

Sandoz net sales in 2016 were $10.1 billion (+1%, +2% in constant currencies, or cc), with strong performance particularly in biopharmaceuticals (+31% cc). An 8 percentage-point increase in volume more than offset the negative 6 percentage-point effect of price erosion. Sales rose in Central and Eastern Europe (+7% cc), Western Europe (+3% cc), the US (+1% cc), Latin America (+11% cc), and the Middle East and Africa (+6% cc). Sales in Asia Pacific were comparable to the prior year (cc).

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	Year ended Dec 31, 2016	Year ended Dec 31, 2015[1]	Change in $	Constant currencies change
	$ m	$ m	%	%
Retail Generics	8,623	8,718	(1)	1
Biopharmaceuticals	1,002	772	30	31
Anti-Infectives (Partner label/API)	519	580	(11)	(10)
Total	**10,144**	**10,070**	**1**	**2**

(1) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

Retail Generics

Sandoz markets active ingredients, intermediates and finished dosage forms of pharmaceuticals. The Retail Generics franchise includes products in the therapeutic areas of dermatology, respiratory, oncology, transplantation and ophthalmics, plus finished dosage forms of anti-infectives sold under the Sandoz name. Franchise sales reached $8.6 billion (+1% cc).

Biopharmaceuticals

Sandoz markets protein- and other biotechnology-based products called biosimilars, as well as *Glatopa,* which treats a relapsing form of multiple sclerosis. Global sales of biopharmaceuticals grew 31% (cc) to $1.0 billion, benefiting from the US launches in 2015 of *Glatopa* and *Zarxio*, and the continued strong growth of other products already on the market.

Anti-Infectives

Sandoz sells pharmaceutical ingredients and intermediates (mainly antibiotics) under the Sandoz name and to third-party customers. Anti-infectives sold to third parties for sale under their own name were $519 million, down 10% (cc), because some low-margin products were discontinued and also due to a weak flu season in the first quarter of 2016. Total Anti-Infectives sales were $1.4 billion, down 2% (cc), and included sales of finished dosage forms sold under the Sandoz name of $860 million, up 4% (cc).

Alcon

Alcon implemented a growth plan in 2016 with emphasis on three areas: accelerating innovation and sales, strengthening customer relationships, and improving operations. Alcon launched new products during the year, including the *CyPass* Micro-Stent to treat glaucoma, the *NGENUITY* 3D Visualization System for retinal surgery, and a multifocal version of its innovative *Dailies Total1* contact lenses. Increased advertising and promotion for contact lenses helped return that segment to growth after several weak quarters.

Alcon net sales in 2016 were $5.8 billion (3%, 2% in constant currencies, or cc).

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	Year ended Dec 31, 2016	Year ended Dec 31, 2015[1]	Change in $	Constant currencies change
	$ m	$ m	%	%
Surgical				
Cataract products	2,695	2,853	(6)	(3)
of which IOLs	*986*	*1,099*	*(10)*	*(7)*
Vitreoretinal products	616	594	4	4
Refractive/other	207	251	(18)	(16)
Total	**3,518**	**3,698**	**(5)**	**(3)**
Vision Care				
Contact lenses	1,762	1,743	1	2
Contact lens care	532	558	(5)	(5)
Total	**2,294**	**2,301**	**0**	**0**
Total net sales	**5,812**	**5,999**	**(3)**	**(2)**

(1) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

Surgical

Surgical sales declined 3% (cc) to $3.5 billion, mainly due to weaker performance of intraocular lenses, which faced competitive pressures, and slowing equipment sales (primarily *LenSx* for cataract surgery and *Wavelight* for refractive surgery, which have reached high penetration in their market segments). Those factors were partially offset by continued solid growth in sales of cataract disposable surgical supplies (4% cc). The Surgical business is making progress, improving service and supply levels in 2016 and laying the foundation for a return to growth.

Vision Care

Vision Care sales were flat in constant currencies at $2.3 billion. Growth in contact lenses offset a decline in contact lens care products. Increased advertising and promotion behind key brands helped return the contact lens segment to growth after several weak quarters. *Dailies Total1*, the first and only water-gradient lens, was the key driver.

Operating Income from Continuing Operations

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

	Year ended Dec 31, 2016	% of net sales	Year ended Dec 31, 2015	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Innovative Medicines[1][2]	**7,426**	**22.8**	**7,815**	**23.4**	**(5)**	**0**
Sandoz[2]	**1,445**	**14.2**	**1,300**	**12.9**	**11**	**14**
Alcon[2]	**(132)**	**(2.3)**	**281**	**4.7**	**nm**	**nm**
Corporate	(471)		(419)		(12)	(25)
	8,268	**17.0**	**8,977**	**18.2**	**(8)**	**(3)**

Operating income from continuing operations	

nm = not meaningful

(1) Formerly named the Pharmaceuticals Division

(2) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

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Operating income was $8.3 billion (8%, 3% cc), a decrease from $9.0 billion in 2015 mainly due to the loss of exclusivity on *Gleevec*, as investments related to new product launches and the Alcon growth plan were partially offset by resource allocation and productivity programs. The negative currency impact of 5% was due to the strong US dollar on average versus the British pound and major emerging market currencies, partially offset by the strengthening of the Japanese yen. Operating income margin in constant currencies decreased 0.7 percentage points; currency had a negative impact of 0.5 percentage points resulting in a decrease of 1.2 percentage points to 17.0% of net sales.

Core Operating Income key figures[(1)]

	Year ended Dec 31, 2016	Year ended Dec 31, 2015	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core gross profit from continuing operations	**35,806**	**36,900**	**(3)**	**(1)**
Marketing & Sales	(11,991)	(11,729)	(2)	(4)
Research & Development	(8,402)	(8,738)	4	3
General & Administration	(2,120)	(2,389)	11	8
Other income	753	823	(9)	(7)
Other expense	(1,059)	(1,077)	2	(1)
Core operating income from continuing operations	**12,987**	**13,790**	**(6)**	**(2)**
As % of net sales	*26.8*	*27.9*		

(1) 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 $4.7 billion (2015: $4.8 billion) broadly in line with the prior year.

Excluding these items, core operating income from continuing operations decreased 6% (2% cc) to $13.0 billion. Core operating income margin in constant currencies decreased 0.7 percentage points mainly due to the loss of exclusivity on *Gleevec*, as investments related to new product launches and the Alcon growth plan were partially offset by resource allocation and productivity programs. Currency had a negative impact of 0.4 percentage points, resulting in a margin of 26.8% of net sales, compared to 27.9% in 2015.

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

	Year ended Dec 31, 2016	% of net sales	Year ended Dec 31, 2015	% of net sales	Change in $	Change in constant currencies
	$ m		$ m		%	%
Innovative Medicines[(1)(2)]	**10,354**	**31.8**	**10,862**	**32.6**	**(5)**	**(1)**
Sandoz[(2)]	**2,071**	**20.4**	**2,045**	**20.3**	**1**	**4**
Alcon[(2)]	**850**	**14.6**	**1,235**	**20.6**	**(31)**	**(27)**
Corporate	(288)		(352)		18	4
Core operating income from continuing operations	**12,987**	**26.8**	**13,790**	**27.9**	**(6)**	**(2)**

(1) Formerly named the Pharmaceuticals Division

(2) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

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Innovative Medicines

Operating income was $7.4 billion (5%, 0% cc).

Core operating income, which excludes certain items, was $10.4 billion (5%, 1% cc). Core operating income margin decreased 0.2 percentage points, mainly due to launch investments for *Entresto* and *Cosentyx*, but partially offset by productivity improvements. Fluctuations in exchange rates had a further negative impact of 0.6 percentage points, resulting in a net decrease of 0.8 percentage points to 31.8% of net sales.

Research and development of Innovative Medicines Division

The following table provides an overview of the reported and core research and development expense of the Innovative Medicines Division:

	Year ended Dec 31, 2016	Year ended Dec 31, 2015[1]	Change in $	Change in constant currencies
	$ m	$ m	%	%
Research and Exploratory Development	(2,645)	(2,739)	3	2
Confirmatory Development	(5,064)	(4,946)	(2)	(4)
Total Innovative Medicines Division Research and Development expense	**(7,709)**	**(7,685)**	**0**	**(2)**
As % of Innovative Medicines net sales to third parties	*23.7*	*23.0*		
Core Research and Exploratory Development[2]	(2,543)	(2,663)	5	3
Core Confirmatory Development[2]	(4,569)	(4,839)	6	4
Total Core Innovative Medicines Division Research and Development expense	**(7,112)**	**(7,502)**	**5**	**4**
As % of Innovative Medicines net sales to third parties	*21.8*	*22.5*		

(1) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016

(2) Core excludes impairments, amortization and certain other items.

Innovative Medicines Division Research and Exploratory Development expense amounted to $2.6 billion in 2016, a decrease of 3% (+2% cc) compared to 2015 as a result of continued productivity efforts. Confirmatory Development expense increased by 2% (4% cc) to $5.1 billion compared to $4.9 billion in 2015, mainly driven by the impairment of intangible assets.

Core Research and Exploratory Development expense in the Innovative Medicines Division as percent of sales decreased by 0.8 percentage points in constant currencies as a result of continued productivity efforts and synergies from acquired Oncology assets. This decrease was partially offset by negative currency movements of 0.1 percentage points, resulting in a net decrease of 0.7 percentage points to 21.8% of net sales.

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Sandoz

Operating income reached $1.4 billion, up 11% (+14% cc).

Core operating income, which excludes certain exceptional items, was $2.1 billion (+1%, +4% cc). Core operating income margin in constant currencies increased 0.2 percentage points. However, that gain was partly offset by the negative 0.1 percentage-point impact of exchange rates, yielding a result of 20.4% of net sales.

Sandoz continued to build its portfolio of biopharmaceuticals, which now represents a $1 billion-plus business, with roughly half of that coming from the US. In 2016, our biosimilar Erelzi (etanercept-szzs) was approved in the US to treat the same inflammatory diseases as the reference product, Amgen's Enbrel®, with its launch pending litigation. In addition, our biosimilar *Binocrit* (epoetin alfa) was approved in the EU for a new route of administration. We are currently evaluating options for an epoetin alfa filing in the US. Filings were accepted in the EU for our pegfilgrastim and rituximab biosimilars.

Alcon

Operating loss was $132 million, compared to an income of $281 million the year before.

Core operating income, which excludes certain items, was $850 million (31%, 27% cc), mainly due to increased investment in research and development, as well as higher spending on sales and marketing both activities that were part of the Alcon growth plan. Core operating income margin in constant currencies decreased by 5.3 percentage points, and exchange rates added another 0.7 percentage points of negative impact, yielding a net decrease of 6 percentage points to 14.6% of net sales.

Corporate Income and Expense, Net

Corporate income and expense, which includes the cost of Group management and central services, amounted to a net expense of $471 million (12%, 25% cc) in 2016 compared to a net expense of $419 million in the prior year. The increase was mainly due to lower royalty and other income as well as costs related to the execution of the initiatives announced on January 27, 2016, to further focus the divisions, centralize manufacturing and integrate drug development functions. These factors more than offset the reduction in General & Administration expenses in 2016.

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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, 2016	Year ended Dec 31, 2015	Change in $	Change in constant currencies
	$ m	$ m	%	%
Operating income from continuing operations	**8,268**	**8,977**	**(8)**	**(3)**
Income from associated companies	703	266	164	164
Interest expense	(707)	(655)	(8)	(10)
Other financial income and expense	(447)	(454)	2	58
Income before taxes from continuing operations	**7,817**	**8,134**	**(4)**	**2**
Taxes	(1,119)	(1,106)	(1)	(13)
Net income from continuing operations	**6,698**	**7,028**	**(5)**	**1**
Net income from discontinued operations		10,766	nm	nm
Net income	**6,698**	**17,794**	**(62)**	**(59)**
Basic EPS ($) from continuing operations	**2.82**	**2.92**	**(3)**	**2**
Basic EPS ($) from discontinued operations		4.48	nm	nm
Total basic EPS ($)	**2.82**	**7.40**	**(62)**	**(59)**

nm = not meaningful

Income from associated companies

Income from associated companies increased to $703 million, compared to $266 million in the prior year.

The increase was mainly due to income recognized from our investment in GSK Consumer Healthcare Holdings Ltd. of $234 million compared to a loss of $79 million recognized in the prior year, in which the income from operations was more than offset by integration charges and an additional expense from the final purchase price allocation for the investment in GSK. The 2016 income contribution from GSK Consumer Healthcare Holdings Ltd. includes a negative adjustment recorded in the second quarter upon the issuance of 2015 actual results.

In addition, in 2016, we recognized an income of $464 million from our investment in Roche, which reflected our estimated share of income for 2016 of $532 million partly offset by the adjustment for 2015 actual results. The higher contribution from Roche in 2016 was mainly due to a smaller adjustment recognized upon publication of 2015 actual results by Roche compared to the adjustment recorded in the prior year upon publication of the 2014 actual results.

Interest Expense and other financial income and expense

Interest expense from continuing operations increased to $707 million from $655 million in the prior year due to higher outstanding debt.

Other financial income and expense amounted to an expense of $447 million compared to $454 million in the prior-year, mainly on account of an exceptional charge of $305 million (2015: $410 million) related to Venezuela due to foreign exchange losses on intra-group payables as well as higher currency losses recognized in 2016.

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Taxes

The tax rate from continuing operations increased to 14.3% from 13.6% in the prior year, mainly as a result of a change in profit mix to jurisdictions with higher tax rates.

Net Income

Net income from continuing operations was $6.7 billion (5%, +1% cc) with the increase of 1% in constant currencies compared to the decline in operating income due to higher income from associated companies, mainly from the investment in GSK Consumer Healthcare Holdings Ltd. The current year includes $0.3 billion (2015: $0.4 billion) exceptional charges related to Venezuela. For more information see " Effects of Currency Fluctuations".

EPS

Basic earnings per share from continuing operations was $2.82 per share (3%, +2% cc), up more than net income due to a reduction in the average number of shares outstanding.

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

Core Non-Operating Income and Expense

	Year ended Dec 31, 2016	Year ended Dec 31, 2015	Change in $	Change in constant currencies
	$ m	$ m	%	%
Core operating income from continuing operations	**12,987**	**13,790**	**(6)**	**(2)**
Core income from associated companies	1,134	981	16	16
Core interest expense	(707)	(655)	(8)	(10)
Core other financial income and expense	(99)	(24)	nm	nm
Core income before taxes from continuing operations	**13,315**	**14,092**	**(6)**	**(2)**
Core taxes	(2,001)	(2,051)	2	(2)
Core net income from continuing operations	**11,314**	**12,041**	**(6)**	**(3)**
Core net loss from discontinued operations		(256)	nm	nm
Core net income	**11,314**	**11,785**	**(4)**	**(1)**
Core basic EPS ($) from continuing operations	**4.75**	**5.01**	**(5)**	**(2)**
Core basic EPS ($) from discontinued operations		(0.11)	nm	nm
Core basic EPS ($)	**4.75**	**4.90**	**(3)**	**0**

nm = not meaningful

Core Income from associated companies

Core income from associated companies increased to $1.1 billion from $981 million in the prior-year period. The increase was due to a higher contribution from GSK Consumer Healthcare Holdings Ltd., which accounted for $369 million in 2016 compared to $213 million in prior-year period.

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Core Interest Expense and other financial income and expense

Core other financial income and expense, which excludes the exceptional charges of $0.3 billion (2015: $0.4 billion) related to Venezuela amounted to a net expense of $99 million, compared to $24 million in 2015.

Core Taxes

The core tax rate from continuing operations (core tax as a percentage of core pre-tax income) increased to 15.0% from 14.6% in the prior year. This increase is mainly a result of a change in core profit mix to jurisdictions with higher tax rates.

Core Net Income

Core net income from continuing operations was $11.3 billion (6%, 3% cc) and decreased 3% in constant currencies, broadly in line with core operating income.

Core EPS

Core basic EPS from continuing operations was $4.75 (5%, 2% cc), down less than core net income due to a reduction in the number of shares outstanding.

Discontinued Operations

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

As all transactions of the portfolio transformation were completed during 2015, there are no results from discontinued operations reported in the 2016 consolidated income statement. In 2015, results for discontinued operations include 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 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 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 income from discontinued operations in the prior year amounted to $10.8 billion. For more information on discontinued operations please see " Factors Affecting Comparability of Year-on Year Results of Operations" below and "Note 29. Discontinued operations" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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Total Group

For the total Group, net income amounted to $6.7 billion compared to $17.8 billion in 2015. The decrease was mainly due to the exceptional divestment gains included in the net income from the discontinued operations of the prior year.

Basic earnings per share decreased to $2.82 from $7.40 in the prior year.

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

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 2017 and 2016 are mentioned below.

Significant transactions in 2017

Innovative Medicines Acquisition of Ziarco Group Limited

On January 20, 2017, Novartis acquired Ziarco Group Limited (Ziarco), a privately held company in the United Kingdom, focused on the development of novel treatments in dermatology. This acquisition adds a once-daily oral H4 receptor antagonist in development for atopic dermatitis, commonly known as eczema, to complement the Novartis dermatology portfolio and pipeline. The fair value of the total purchase consideration was $420 million. The amount consisted of an initial cash payment of $325 million and the net present value of the contingent consideration of $95 million, due to Ziarco shareholders, which they are eligible to receive upon the achievement of specified development milestones. The purchase price allocation resulted in net identifiable assets of $395 million and goodwill of $25 million. Results of operations since the date of acquisition were not material.

Innovative Medicines Acquisition of Encore Vision, Inc.

On January 20, 2017, Novartis acquired Encore Vision, Inc. (Encore), a privately-held company in Fort Worth, Texas, in the United States, focused on the development of a novel treatment in presbyopia. The fair value of the total purchase consideration was $456 million. The amount consisted of an initial cash payment of $366 million and the net present value of the contingent consideration of $90 million, due to Encore shareholders, 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 $389 million and goodwill of $67 million. Results of operations since the date of acquisition were not material.

Significant transactions in 2016

Alcon Acquisition of TRANSCEND MEDICAL, INC.

On February 17, 2016, Alcon entered into an agreement to acquire Transcend Medical, Inc. (Transcend), a privately-held, US-based company focused on developing minimally-invasive surgical devices to treat glaucoma. The transaction closed on March 23, 2016, and the fair value of the total purchase consideration was $332 million. The amount consisted of an initial cash payment of $240 million and the net present value of the contingent consideration of $92 million due to Transcend shareholders, 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 $294 million and goodwill of $38 million. The 2016 results of operations since the date of acquisition were not material.

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Innovative Medicines Acquisition of REPRIXYS PHARMACEUTICALS CORPORATION

On November 18, 2016, Novartis acquired Reprixys Pharmaceuticals Corporation (Reprixys), a privately held, US-based company specializing in the development of therapeutics in certain hematologic and inflammatory disorders, following receipt of results of the SUSTAIN study. The initial interest of 19% was adjusted to its fair value of $64 million through the consolidated income statement at acquisition date. This re-measurement resulted in a gain of $53 million.

The fair value of the total purchase consideration for acquiring the 81% stake Novartis did not already own amounted to $268 million. The amount consisted of an initial cash payment of $194 million and the net present value of the contingent consideration of $74 million due to Reprixys shareholders, 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 $332 million. No goodwill was recognized. The 2016 results of operations since the date of acquisition were not material.

For further details on significant transactions, see "Note 2. Significant transactions" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are set out in "Note 1. Significant accounting policies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018, 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 pharmaceutical industry, our gross sales are subject to various deductions which are primarily composed 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 judgement 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 pricing and the mix of contracts and specific terms in the individual State agreements.

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The United States Federal Medicare Program, which funds healthcare benefits to individuals age 65 or older and certain disabilities, provides prescription drug benefits under Part D section of the program. This benefit is provided and administrated 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 pricing and the mix of contracts.

We offer rebates to key managed healthcare and private plans in an effort to sustain and increase market share of our products, and to ensure patient access. These programs provide a rebate after the plans 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, product pricing, and projected product growth rates. These provisions are adjusted based on established processes and experiences from filing data with individual states and plans. There is often a time lag of several months between us recording the revenue deductions and our final accounting for them.

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, especially in Europe and Australia, we enter into innovative pay-for-performance arrangements with certain healthcare providers. 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 assistance 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

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

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 for the estimate of charge-backs attributable to a sale transaction. Provisions for estimated charge-backs are calculated using a combination of factors such as historical experience, product growth rates, payments, product pricing, level of inventory in the distribution channel, the terms of individual agreements and our estimate of the claims processing time lag.

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 return policy and historical return 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 2017, 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.

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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' inventory levels consistent with underlying patient demand.

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

Following a decrease in the price of a product, we generally grant customers a "shelf stock adjustment" for their 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 amounts of these discounts are recorded at the time of sale, or when the coupons are 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 inventory in transit, the level of inventory in the distribution and retail channels actual claims data received and the time lag for processing rebate claims. External data sources include reports from 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 Innovative Medicines, Sandoz and Alcon Divisions:

PROVISIONS FOR DEDUCTIONS FROM REVENUE

	Revenue deductions provisions at January 1	Effect of currency translation and business combinations	Payments/ utilizations	Income statement charge: Adjustments of prior years	Income statement charge: Current year	Change in provisions offset against gross trade receivables	Revenue deductions provisions at December 31
	$ m	$ m	$ m	$ m	$ m	$ m	$ m
2017							
US-specific healthcare plans and program rebates	1,461		(3,684)	(62)	3,875		1,590
Non-US-specific healthcare plans and program rebates	1,020	131	(1,954)	80	2,186	(107)	1,356
Non-healthcare plans and program-related rebates, returns and other deductions	1,702	65	(11,814)	(127)	12,045	(145)	1,726
Total continuing operations 2017	**4,183**	**196**	**(17,452)**	**(109)**	**18,106**	**(252)**	**4,672**
2016							
US-specific healthcare plans and program rebates	1,165		(3,203)	7	3,492		1,461
Non-US-specific healthcare plans and program rebates	1,024	(31)	(1,844)	(26)	1,883	14	1,020
Non-healthcare plans and program-related rebates, returns and other deductions	1,601	(19)	(11,142)	(117)	11,383	(4)	1,702
Total continuing operations 2016	**3,790**	**(50)**	**(16,189)**	**(136)**	**16,758**	**10**	**4,183**
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**

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The table below shows the gross to net sales reconciliation for our Innovative Medicines 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	
2017				
Innovative Medicines gross sales subject to deductions			**43,994**	**100.0**
US-specific healthcare plans and program rebates	(3,303)		(3,303)	(7.5)
Non-US-specific healthcare plans and program rebates	(1,722)	(956)	(2,678)	(6.1)
Non-healthcare plans and program-related rebates, returns and other deductions	(2,698)	(2,290)	(4,988)	(11.3)
Total Innovative Medicines gross to net sales adjustments	**(7,723)**	**(3,246)**	**(10,969)**	**(24.9)**
Innovative Medicines net sales 2017			**33,025**	**75.1**
2016				
Innovative Medicines gross sales subject to deductions			**42,630**	**100.0**
US-specific healthcare plans and program rebates	(3,051)		(3,051)	(7.2)
Non-US-specific healthcare plans and program rebates	(1,352)	(885)	(2,237)	(5.2)
Non-healthcare plans and program-related rebates, returns and other deductions	(2,736)	(2,044)	(4,780)	(11.2)
Total Innovative Medicines gross to net sales adjustments	**(7,139)**	**(2,929)**	**(10,068)**	**(23.6)**
Innovative Medicines net sales 2016			**32,562**	**76.4**
2015[(1)]				
Innovative Medicines gross sales subject to deductions			**42,460**	**100.0**
US-specific healthcare plans and program rebates	(2,533)		(2,533)	(6.0)
Non-US-specific healthcare plans and program rebates	(1,238)	(762)	(2,000)	(4.7)
Non-healthcare plans and program-related rebates, returns and other deductions	(2,831)	(1,751)	(4,582)	(10.8)
Total Innovative Medicines gross to net sales adjustments	**(6,602)**	**(2,513)**	**(9,115)**	**(21.5)**
Innovative Medicines net sales 2015			**33,345**	**78.5**

(1) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016.

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Surgical Equipment Revenue

Surgical equipment is often sold together with other products and services under a single contract. The total consideration is allocated to the separate elements based on their relative fair values. Revenue is recognized once the recognition criteria have been met for each element of the contract.

For surgical equipment, in addition to cash and instalment sales, revenue is recognized under finance and operating lease arrangements. Arrangements in which Novartis transfers substantially all the risks and rewards incidental to ownership to the customer are treated as finance lease arrangements. Revenue from finance lease arrangements is recognized at amounts equal to the fair values of the equipment, which approximate the present values of the minimum lease payments under the arrangements. As interest rates embedded in lease arrangements are approximately market rates, revenue under finance lease arrangements is comparable to revenue for outright sales. Finance income for arrangements in excess of twelve months is deferred and subsequently recognized based on a pattern that approximates the use of the effective interest method and recorded in "Other income". Operating lease revenue for equipment rentals is recognized on a straight-line basis over the lease term.

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 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;
- behavior of competitors (launch of competing products, marketing initiatives, etc.);
- probability of obtaining regulatory approvals;
- future tax rates;
- appropriate royalty rate for the Alcon brand name;
- appropriate terminal growth rate; and
- appropriate discount rate.

Due to the above factors and those further described in "Note 1. Significant accounting policies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018, actual cash flows and values could vary significantly from forecasted future cash flows and related values derived using discounting techniques.

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The recoverable amount of the grouping of cash generating units to which goodwill and indefinite life intangible assets are allocated is based on fair value less costs of disposal. The valuations are derived from applying discounted future cash flows based on key assumptions, including the terminal growth rate and discount rate. For additional information see "Note 10. Goodwill and intangible assets" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

In 2017, intangible asset impairment charges of $709 million were recognized, of which $591 million was recorded in the Innovative Medicines Division, $61 million in the Sandoz Division, and $57 million in the Alcon Division.

In 2016, intangible asset impairment charges for continuing operations of $591 million were recognized, of which $522 million was recorded in the Innovative Medicines Division, $65 million in the Sandoz Division, and $4 million in the Alcon Division.

In 2017 and in 2016, there were no reversals of prior-year impairment charges.

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 "Note 10. Goodwill and intangible assets" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Additionally, net impairment charges for property, plant and equipment during 2017 amounted to $157 million (2016: $102 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 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, Brazil, Russia, Saudi Arabia, Turkey and other countries, and evaluates trade receivables in these countries for potential collection risks. Substantially all of the trade receivables overdue from Greece, Italy, Portugal, Spain and Saudi Arabia are due directly from local governments or from government-funded entities. Deteriorating credit and economic conditions as well as 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 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 financial 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, are appropriately discounted to reflect the impact of time.

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Changes in the fair value of contingent consideration 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 In-Process Research and Development (IPR&D). Changes in contingent consideration assets are recognized in "Other income" or "Other expense", depending on its nature.

The effect of unwinding the discount over time is recognized for contingent liabilities in "Interest expense" and for contingent assets in "other financial income and expense" in the consolidated income statement.

Impairment of Associated Companies Accounted for at Equity

Novartis considers investments in associated companies for impairment evaluation whenever objective evidence indicates the net investment may be impaired, including when a quoted share price indicates a fair value less than the per-share balance sheet carrying value for the investment.

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.

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 2017, 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, United States, United Kingdom, Germany and Japan, which represent 94% of the Group total defined benefit pension obligation, by approximately $0.8 billion. Similarly, if the 2017 interest rate had been one quarter of one percentage point lower than actually assumed, the net periodic pension cost for pension plans in these countries, which represent about 82% of the Group's total net periodic pension cost for pension plans, would have increased by approximately $23 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 "Note 24. Post-employment benefits for associates" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

Provisions and 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 "Note 19. Provisions and other non-current liabilities" and "Note 27. Commitments and contingencies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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We record provisions for legal proceedings when it is probable that a liability has been incurred and the amount can be reliably estimated. These provisions are adjusted periodically as assessments change or additional information becomes available. For significant product liability cases, the provision 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.

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

Healthcare Contributions

In many countries, our subsidiaries are required to make contributions to the countries' healthcare costs as part of programs other than the ones mentioned 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".

In addition, effective 2013, the United States government implemented a medical device sales tax that is levied on the Alcon Division's United States sales of products which that 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. In December 2015, Congress enacted a law that included a two-year moratorium on applying the medical device excise tax, which expired on December 31, 2017. On January 22, 2018, the US Congress extended the moratorium for an additional two years.

Taxes

We prepare and file our tax returns based on an interpretation of tax laws and regulations, and we 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. Since Novartis uses its intellectual property globally to deliver goods and services, the transfer prices within the Group as well as arrangements between subsidiaries to finance research and development and other activities may be challenged by the national tax authorities in any of the jurisdictions in which Novartis operates. Therefore, inherent uncertainties exist in our estimates of our tax positions, but 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.

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New Accounting Pronouncements

See "Note 1. Significant accounting policies" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

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, 2017.

FACTORS AFFECTING RESULTS OF OPERATIONS

Transformational Changes Fueling Demand

Accelerating biomedical innovation

We are seeing an explosion of innovation in medical science. Better understanding of the molecular mechanisms of disease, coupled with new types of therapies, promises to yield powerful new medicines for patients. The trend toward patient-specific precision treatments will likely accelerate.

Further advances in molecular biology, which has been a mainstay of research for decades, will continue to yield results. Scientists contributing to the Human Protein Atlas have identified about 1 800 proteins that they believe are possible targets for drugs. So far, only about 600 of them are actually targeted by currently approved therapies. In addition, new molecular techniques, such as gene editing, personalized cell therapies and harnessing the cell's own waste disposal system, could open new treatment opportunities including ones that go beyond what has been possible using today's drugs.

The advent of digital technologies as therapeutic aids is also starting to alter the conventional notion of medical treatment. For instance, mobile applications that aim to treat substance abuse and help diabetics manage their disease have received clearance from the US Food and Drug Administration (FDA). Combining traditional medicines with digital technology that helps patients follow healthy behaviors holds great promise for improving the quality of care as well as treatment outcomes for patients.

Transforming how doctors diagnose and treat diseases

Although the digital revolution has been relatively slow to arrive in healthcare, it is gaining momentum and will likely bring radical change in the coming years.

A growing proliferation of sensor technology is helping researchers and doctors gather increasing amounts of information about patients' health and how they respond to treatment. Care providers are starting to mine healthcare data using a combination of statistical methods and artificial intelligence to flag emerging medical problems and help physicians diagnose and treat patients. In fact, a recent study found that computers already have an edge over doctors in their ability to predict the likelihood that a patient will have a heart attack over a 10-year period, based on an evaluation of risk factors.

Patients, armed with greater access to their own medical data, will likely play a more active role in preventing diseases and managing their own care when they become ill. The role of physicians and other care providers will likely also evolve as they help educate patients on treatment options and steer patients toward the most effective choices.

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Transforming drug research and development

Digital technology may also increasingly improve the efficiency and effectiveness of researching and developing potential new therapies. The marriage of data and artificial intelligence will enable complex biological simulations that complement human scientific ingenuity. Such tools are already being considered by the FDA as replacements for preclinical animal studies to assess toxicity in potential new medicines. As digital tools become more widespread, they may be able to shorten research times and improve the likelihood that experimental drugs will prove safe and effective.

This surge in medical innovation will likely occur in an increasingly diverse and fragmented research environment, with new advances coming from a variety of sources sometimes unexpected ones. Molecular biology may intersect with other disciplines, from engineering to computer science, to advance the practice of medicine. And we expect there will be greater diversity in funding for research. Already we see governments, companies and venture capitalists increasingly supporting academic researchers' efforts to advance promising experimental therapies.

All of these factors are contributing to greater competition at the forefront of innovation in medical science. One upshot is that medicines will likely be held to a higher standard of efficacy in the future.

Aging populations

While accelerating medical innovation could help tame some of the devastating diseases that still plague humanity, other trends in society pose significant challenges. Rapidly aging populations continue to put pressure on health systems around the world.

People are living longer and the worldwide elderly population continues to grow at a rapid pace. The number of people in the world over age 60 will reach about 1.4 billion by 2030, according to projections by the United Nations, up from less than 1 billion today. Aging populations, in addition to rapid urbanization and changing lifestyles in the developing world, are contributing to increased prevalence of chronic ailments such as heart disease and cancer.

At the same time, many countries are working to expand access to healthcare. For example, China recently expanded reimbursement of some medicines.

These factors are driving higher healthcare spending, which is expected to grow at an annual rate of 4.3% between 2015 and 2020, reaching a total of $8.7 trillion worldwide, projects the Economist Intelligence Unit. By 2020, about half of that spending is expected to go toward treating the three leading causes of death worldwide: cardiovascular disease, cancer and respiratory disease.

To keep costs in check, governments and health insurers are already employing a variety of tactics, including increasing the use of generics and biosimilars, imposing price cuts, and limiting access to some innovative therapies. The pharmaceutical industry is also playing a role, exploring new pricing models and delivering innovative new treatments that maximize benefits for patients.

Better health outcomes for patients

In pursuit of greater efficiency and effectiveness, some healthcare systems are also expediting the transition from a system based on fees for services toward one based on reimbursement for specific health outcomes in patients. In the US, for instance, a new law came into effect in 2017 that aims to tie reimbursement more closely to quality and health outcomes for some elderly patients.

As the transition accelerates, we expect health systems will increasingly find ways to discourage the use of medical treatments that bring little or no value for patients or healthcare systems. In parallel, they will likely place greater value on treatments that delay the progression of disease or that help avoid events requiring expensive acute care, such as heart attacks.

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With people living longer and retirement ages rising, we also anticipate countries and health systems will put greater emphasis on keeping people fit and productive later in life. And we think there will be growing emphasis on maintaining quality of life as people age, with less focus on extending life by a few more months.

For more detailed discussion about the risks facing Novartis and what we're doing to mitigate them, see " Increasingly Challenging Business Environment" below.

We think the trends driving changes in healthcare will bring new opportunities for Novartis, as well as new challenges. And we believe the changes now underway in our industry raise the importance of delivering true innovation that produces better health outcomes for patients and health systems, with greater efficiency.

Increasingly Challenging Business Environment

Loss of exclusivity for patented products

Pharmaceutical companies routinely face generic competition when their products lose patent or other intellectual property protection, and Novartis is no exception. Major products of our Innovative Medicines Division, as well as certain products of our Alcon and Sandoz Divisions, are 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 2017, the impact of generic competition on our net sales amounted to approximately $2.0 billion.

Some of our best-selling products face or are expected to face considerable competition due to the expiration of patent or other intellectual property protection. For example, we faced generic competition for *Gleevec/Glivec* in the United States, European Union and Japan throughout 2017, which will continue. Patent protection for our *Sandostatin* products has expired and generic versions of *Sandostatin* SC are available in the United States, European Union and Japan. Diovan and Co-Diovan/Diovan HCT, which had long been our best-selling products, have generic competitors in the United States, European Union and Japan. Looking forward, intellectual property protecting a number of our major products will expire at various times in the coming years, raising the likelihood of further generic competition. Among our products expected to begin losing intellectual property in key countries during the next three years are *Gilenya*, our everolimus products (*Afinitor/Votubia* and *Certican/Zortress*), *Exjade/Jadenu* and *Lucentis*.

To counter the impact of patent expirations, we continuously invest in R&D to rejuvenate our portfolio. For example, in 2017, we invested 18.3% of total net sales in R&D. One measure of the output of our efforts is the performance of our growth drivers, including *Cosentyx* and *Entresto*, the launches of *Kisqali*, *Kymriah* and *Rydapt* in 2017, and the newly launched Sandoz biosimilars. Novartis also has a number of late-stage product candidates in its pipeline with the potential to come to market in the next few years.

Ability to deliver new products

Our ability to maintain and grow our business and to replace revenue and income lost to generic and other competition depends in part on the success of our R&D activities in identifying and developing new treatments, that address unmet medical needs, are accepted by patients and physicians, and are reimbursed by payors.

Developing new healthcare products and bringing them to market is a costly, lengthy and uncertain process. R&D for a new product in our Innovative Medicines Division can take 15 years or more, from discovery to commercial launch. With time limits on intellectual property protections, the longer it takes to develop a product, the less time we may have to recoup our costs. During each stage of development, there is a significant risk that we will encounter obstacles. They may cause a delay or add substantial

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expense, limit the potential for commercial success, or force us to abandon a product in which we have invested substantial amounts of time and money.

In addition, as healthcare costs continue to rise, governments and payors around the world are increasingly focused on health outcomes, rewarding new products that represent truly breakthrough innovation versus those that offer an incremental benefit over other products in the same therapeutic class. This has led to requests for more clinical trial data than has been required in the past, the inclusion of significantly higher numbers of patients in clinical trials, and more detailed analyses of the trials. As a result, despite significant efforts by health authorities such as the FDA to accelerate the development of new drugs, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has become even more challenging.

Our Sandoz Division faces similar challenges, particularly in the development of biosimilars. While Sandoz was a pioneer in introducing biosimilars to the European market in 2006, and was the first company to win approval for a biosimilar under the new regulatory pathway in the United States in 2015, many countries still lack fully developed regulatory frameworks for the development and approval of biosimilars. Further delays in establishing regulatory frameworks, or any other difficulties that may arise in the development or marketing of biosimilars, could put at risk the significant investments that Sandoz has made, and will continue to make, in this area.

Our Alcon Division faces medical device development and approval processes that are often similarly difficult. As part of its growth plan, Alcon has taken steps to accelerate innovation. It has started to see the results of its efforts, with the approval and launch of intraocular lens innovations in 2016 and 2017, including *Clareon* and *PanOptix* IOLs, *AutonoMe* and *Ultrasert* IOL delivery systems, and, *ReSTOR* Toric IOL with *ACTIVEFOCUS* optical design, as well as *CyPass* micro-stent and a multifocal version of *Dailies Total1*. But there is no certainty that Alcon will continue to be successful in these efforts, and if it is not, there could be a material adverse effect on the success of the Alcon Division, and on the Group as a whole.

In spite of our significant investments, there can be no guarantee that our R&D activities will produce commercially viable new products that will enable us to grow our business and replace revenue and income lost to competition.

Commercial success of key products

Our ability to grow depends not only on our pipeline delivery, but also on our commercial success, particularly with respect to our key growth drivers, which we consider to be an indicator of our ability to renew our portfolio. The commercial success of these products could be impacted at any time by a number of factors, including new competitors, changes in doctors' prescribing habits, pricing pressure, manufacturing issues, and loss of intellectual property protection. In addition, our revenue could be significantly impacted by the timing and rate of commercial acceptance of new products.

All of our businesses face intense competition from new products and scientific advances from competitors. Physicians, patients and payors may choose competitor products instead of ours if they perceive them to be better in terms of efficacy, safety, cost or convenience.

In particular, our Alcon Division and our US Sandoz business each has suffered declines in sales and profits in recent years due at least in part to increased competition for its products, although Alcon's results improved in 2017, returning to growth. There can be no certainty either that Sandoz US sales will recover, or that Alcon's improved results will be repeated in the coming years. In any event, such competition and the costs of our efforts to improve these businesses' performance, as well as other factors, can be expected to affect the business, financial condition or results of operations of these organizations, at least in the near term. In addition, despite the devotion of significant resources to our efforts to improve the performance of Alcon and Sandoz US, those efforts may ultimately prove insufficient.

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Pricing and reimbursement

Around the world, governments and payors continue to struggle with rising healthcare costs as aging populations contribute to increased prevalence of chronic diseases. There have also been examples of significant controversies about prices for pharmaceuticals that some members of the public have considered excessive. These factors have intensified the pressures we face regarding the prices we charge for our drugs, and our ability to establish satisfactory rates of reimbursement for our products by governments, insurers and other payors.

In our Sandoz Division, for example, sales declined in 2017 due to intense industry pricing pressure in the US. Sales growth outside the United States was unable to fully compensate.

We expect scrutiny to continue in 2018, and the following years, as governments and insurers around the world strive to reduce healthcare costs through steps such as restricting access to higher-priced new medicines, increasing coinsurance or copays owed by patients for medicines, increasing the use of generics, and imposing price cuts. In this environment, we believe it is more important than ever to demonstrate the value that true innovation brings to the healthcare system.

To manage these pressures, we are investing in real-world data and analytics to provide additional evidence of the health benefits of our products, exploring new technologies and patient management services, and partnering with payors to develop and scale outcomes-based commercial models. For example, we are working with customers on flexible pricing approaches where we are fully compensated only if a drug succeeds in meeting certain performance targets.

Business practices

In recent years, there has been a trend of increasing government investigations and litigation against companies operating in our industry, including in the United States and other countries. We are obligated to comply with the laws of all countries in which we operate, as well as any new requirements that may be imposed upon us. But beyond legal requirements, we strive to meet evolving public expectations for ethical behavior. We have a significant global compliance program in place, and we devote substantial time and resources to efforts to ensure that our business is conducted in a legal and publicly acceptable manner. Despite these 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 compliant. For example, sponsoring doctors to attend medical conferences has long been used by pharmaceutical companies to help raise awareness of the latest advances in medicine. One of our goals in 2017 was to find better and more inclusive ways to reach a broader cross-section of this community. We have therefore started to employ technology to supplement face-to-face meetings and bring the experience of international congresses to the local level.

Responding to these challenges and new regulations is costly. Investigations and litigation may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the United States and other countries, and potentially lead to large damage payments and agreements intended to regulate company behavior. This is why we continued to strengthen the Integrity & Compliance function in 2017. The function now has 473 employees and is headed by our Chief Ethics and Compliance Officer, who reports directly to the CEO of Novartis. The Chief Ethics and Compliance Officer is also Head of Litigation, reporting to the Group General Counsel of Novartis. By bringing the Integrity & Compliance and Legal functions closer together, we can evaluate facts that might be at issue in lawsuits to determine if additional compliance actions or policies are warranted. We expect this will help us constantly improve our compliance activities.

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Supply continuity

The production of pharmaceutical products and medical devices can be highly complex, and any manufacturing issue compromising supply or quality could have serious consequences for the health of patients. For this reason, there are strict regulatory requirements surrounding our manufacturing processes, which, in addition to our own high quality standards, introduce a greater chance for disruptions and liabilities. Any significant failure by us or our third party suppliers to comply with these requirements or the health authorities' expectations, may cause us to shut down the production facilities or production lines. Alternately, we may be forced to shut them down by a government health authority.

Beyond regulatory requirements, many of our products involve technically sophisticated manufacturing processes or require specialized raw materials. For example, biologic products, produced from living plant or animal micro-organisms comprise a significant portion of our product portfolio. For biologic products, slight deviations in the production process could lead to production failures or recalls. Our 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 such products.

Given the complexity of our manufacturing processes, we have worked for several years to adopt a single high-quality standard across the company. We believe these efforts are having an impact. The results of inspections by regulatory agencies in 2017 were consistent with the year before. Out of a total of 217 inspections, all but two (99%) were without major findings.

Foreign exchange fluctuations

Changes in exchange rates between the US dollar, our reporting currency, and other currencies can have a significant effect on our reported sales, costs and earnings, as well as on the reported value of our assets, liabilities and cash flows.

For example, because our expenditures in Swiss francs are significantly higher than our revenue in Swiss francs, volatility in the value of the Swiss franc can have a significant impact on our reported results, and the timing and extent of such volatility can be difficult to predict.

There is also a risk that certain countries could take steps that could significantly impact the value of their currencies, such as withdrawing from trade agreements or common currencies. In addition, countries facing local financial difficulties, including countries experiencing high inflation rates and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Such exchange controls could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries.

To mitigate the risk posed by foreign exchange fluctuations, we engage in hedging transactions where management deems appropriate, after taking into account the natural hedging afforded by our global business activity.

Intangible assets and goodwill

We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, primarily due to acquisitions, including the acquisition of Alcon and the oncology assets acquired from GSK. As a result, we may incur significant impairment charges if the fair value of intangible assets and groupings of cash generating units containing goodwill are 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 for impairment. In 2017, for example, we recorded intangible asset impairment charges of $709 million, including the cost of discontinuing the development of RLX030 (serelaxin). Impairment testing may lead to additional

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impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations and financial condition.

Tax

Our worldwide operations are taxed under the laws of the jurisdictions in which we operate. However, the integrated nature of our worldwide operations can produce conflicting claims from revenue authorities in different countries as to the profits to be taxed in the individual countries, including disputes relating to transfer pricing. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untried, and can be expected to be very lengthy.

In recent years, tax authorities around the world have increased their scrutiny of company tax filings, and have become more rigid in exercising any discretion they may have. As part of this, the Organization for Economic Co-operation and Development (OECD) has proposed a number of tax law changes under its Base Erosion and Profit Shifting (BEPS) Action Plans to address issues of transparency, coherence and substance.

At the same time, the European Commission is finalizing its Anti Tax Avoidance Directive, which seeks to prevent tax avoidance by companies and to ensure that companies pay appropriate taxes in the markets where profits are effectively made and business is effectively performed. The European Commission also continues to extend the application of its policies seeking to limit fiscal aid by Member States to particular companies, and the related investigation of the Member States' practices regarding the issuance of rulings on tax matters relating to individual companies.

These OECD and EU tax reform initiatives also need local country implementation, including in our home country of Switzerland, which may result in significant changes to established tax principles. Although we have taken steps to be in compliance with the evolving OECD and EU tax initiatives, and will continue to do so, significant uncertainties remain as to the outcome of these efforts.

In addition, in the United States, the president on December 22, 2017, signed into law the Tax Cuts and Jobs Act of 2017, which includes substantial changes to the US taxation of individuals and businesses. Although the new law substantially decreased tax rates applicable to corporations, we do not yet know what all of the consequences of this new statute will be, including whether the law will have any unintended consequences. In particular, significant uncertainties remain as to how the US government will implement the new law, including with respect to the tax qualification of interest deductions, the concept of a territorial tax regime, royalty payments and cost of goods sold.

In general, such tax reform efforts, including with respect to tax base or rate, transfer pricing, intercompany dividends, cross border transactions, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, will require us to continually assess our organizational structure against tax policy trends, and could lead to an increased risk of international tax disputes and an increase in our effective tax rate, and could adversely affect our financial results.

IT security, data integrity and data privacy

We are heavily dependent on critical, complex and interdependent information technology (IT) systems, including internet-based systems, to support business processes.

The size and complexity of our IT systems, and in some instances their age, make them potentially vulnerable to external and internal security incidents, breakdowns, malicious intrusions, cybercrimes, including State-sponsored cybercrimes, malware, misplaced and lost data, programming and human errors, and other similar events. Although we have devoted and continue to devote significant resources and management attention to cybersecurity and to business continuity efforts, like many companies, we

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have experienced certain of these events and expect to continue to experience them in the future, as the external cyber-attack threaat only keeps growing. We believe that the data security incidents we have experienced to date have not resulted in significant disruptions to our operations, and have not had a significant adverse effect on our results of operations, or on third parties. However, we may not be able to prevent breakdowns or breaches in our systems and we may not be able to prevent such events from having a material adverse effect on our business, financial condition, results of operation, or reputation.

In addition, our routine business operations, including through the use of information technologies such as the Internet, social media, mobile technologies, and technology-based medical devices, increasingly involve our gathering personal information (including sensitive personal information) about patients, vendors, customers, employees, collaborators and others. Breaches of our systems or those of our third-party contractors, or other failures to protect such information, could expose such people's personal information to unauthorized persons. Any such event could give rise to significant potential liability and reputational harm, including potentially substantial monetary penalties. We also make significant efforts to ensure that any international transfers of personal data are done in compliance with applicable law. Any additional restraints 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.

Transformational technologies and business models

Rapid progress in digital technologies and in the development of new business models is substantially transforming numerous industries around the world, while sometimes quickly rendering established businesses uncompetitive or obsolete. To take advantage of these opportunities, Novartis has embarked upon a digital transformation strategy, with the goal of making Novartis an industry leader in leveraging advanced analytics and other new technologies. At the same time, there is a risk that other companies with specialized expertise or business models may enter the healthcare field, potentially disrupting our relationships with patients, healthcare professionals, customers, distributors and suppliers, with unknown potential consequences for us.

If we should fail to succeed in our efforts at a digital transformation of our company, then there is a risk that we may fail to create the innovative new products, tools or techniques that such technologies may make possible, or may fail to create them as quickly and efficiently as such technologies may enable. We may also lose opportunities to engage with our stakeholders and to profit from improved business processes, and may lose the resources devoted to these efforts to transform our business. At the same time, should third parties successfully enter the healthcare field with disruptive new technologies or business models, then we potentially may see our business supplanted in whole or in part by these new entrants.

Approach to Risk Management

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 in 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, organizational units, and functions, with specialized Corporate functions, such as Group Finance, Group Legal, Group Quality Assurance, Corporate Health, Safety and Environment, Business Continuity Management, Integrity & Compliance and the Business Practices Office providing support and controlling the effectiveness of risk management in these areas.

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Financial risk management is described in more detail in "Note 28. Financial instruments additional disclosures" in the "Excerpts from Novartis Annual Report 2017" furnished to the SEC on Form 6-K on January 24, 2018.

NON-IFRS MEASURES AS DEFINTED 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 fully the amortization and impairment charges of intangible assets, except software, and certain acquisition-related items. The following items that exceed a threshold of $25 million are also excluded: integration and divestment related income and expenses, divestment gains and losses, restructuring charges/releases and related items, legal related items, impairments of property, plant and equipment and financial assets, as well as 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 since they exclude items that can vary significantly from year to 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, divestments, or amortization/impairments of purchased intangible assets and restructurings.

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.

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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-US dollar functional currencies to US dollars; 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 US dollars, using the average exchange rates from the prior year and comparing them to the prior year values in US dollars.

We use these constant currency measures in evaluating the Group's performance, since they may assist us in evaluating our ongoing performance from year to year. However, in performing our evaluation, we also consider equivalent measures of performance that 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

Free cash flow is presented as additional information because management believes it is a useful supplemental 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. Free cash flow is a non-IFRS measure, which means it should not be interpreted as a measure determined under IFRS. Free cash flow is not intended to be a substitute measure for cash flow from operating activities as determined under IFRS.

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, as well as intangible, other non-current and financial assets, excluding marketable securities. The definition of free cash flow used by Novartis does not include amounts related to changes in investments in associated companies or related acquisitions or divestments of subsidiaries.

Net Debt

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. Net debt is a non-IFRS measure, which means it should not be interpreted as a measure determined under IFRS.

Novartis defines net debt as current and non-current financial debt less cash and cash equivalents, current investments and derivative financial instruments.

Novartis Cash Value Added

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 Long-Term Performance Plan introduced in 2014.

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More information on NCVA is presented as part of the Compensation Report, see "Item 6.B Compensation".

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).

	2017	2016	Change
	$ m	$ m	$ m
Operating income	**8,629**	**8,268**	**361**
Depreciation of property, plant & equipment	1,520	1,489	31
Amortization of intangible assets	3,690	3,861	(171)
Impairments of property, plant & equipment, and intangible assets	866	693	173
EBITDA	**14,705**	**14,311**	**394**

Enterprise value

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

	Dec 31, 2017	Dec 31, 2016	Change
	$ m	$ m	$ m
Market capitalization	195,541	172,048	23,493
Non-controlling interests	59	59	0
Financial debts and derivatives	28,532	23,802	4,730
Liquidity	(9,485)	(7,777)	(1,708)
Enterprise value	**214,647**	**188,132**	**26,515**
Enterprise value/EBITDA	**15**	**13**	

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2017 AND 2016 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS

	Innovative Medicines		Sandoz		Alcon		Corporate		Group	
	2017	2016	2017	2016	2017	2016	2017	2016	2017	2016
	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m
IFRS Operating income	**7,782**	**7,426**	**1,368**	**1,445**	**(190)**	**(132)**	**(331)**	**(471)**	**8,629**	**8,268**
Amortization of intangible assets	**2,243**	**2,440**	**454**	**460**	**901**	**901**			**3,598**	**3,801**
Impairments										
Intangible assets	591	522	61	65	57	4			709	591
Property, plant & equipment related to the Group-wide rationalization of manufacturing sites	7	1	60	(7)					67	(6)
Other property, plant & equipment	77	76	13	8					90	84
Financial assets		18			29		197	99	226	117
Total impairment charges	**675**	**617**	**134**	**66**	**86**	**4**	**197**	**99**	**1,092**	**786**
Acquisition or divestment of businesses and related items ..										
Income	(2)	(68)					(115)	(229)	(117)	(297)
Expense	32	41					130	223	162	264
Total acquisition or divestment of businesses and related items, net	**30**	**(27)**					**15**	**(6)**	**45**	**(33)**
Other items										
Divestment gains	(368)	(608)		(6)				(48)	(368)	(662)
Restructuring and related items										
Income	(53)	(41)	(7)	(23)	(4)	(4)	(1)	(5)	(65)	(73)
Expense	268	418	134	123	34	33	29	65	465	639
Legal-related items										
Income	(21)	(99)							(21)	(99)
Expense	35	205			61				96	205
Additional income	(534)	(61)	(3)		(51)	(13)	(372)	(22)	(960)	(96)
Additional expense	273	84		6	20	61	46	100	339	251
Total other items	**(400)**	**(102)**	**124**	**100**	**60**	**77**	**(298)**	**90**	**(514)**	**165**
Total adjustments	**2,548**	**2,928**	**712**	**626**	**1,047**	**982**	**(86)**	**183**	**4,221**	**4,719**
Core operating income	**10,330**	**10,354**	**2,080**	**2,071**	**857**	**850**	**(417)**	**(288)**	**12,850**	**12,987**
as % of net sales	*31.3%*	*31.8%*	*20.7%*	*20.4%*	*14.2%*	*14.6%*			*26.2%*	*26.8%*
Income from associated companies	(1)		23	6			1,086	697	1,108	703
Core adjustments to income from associated companies, net of tax	1						226	431	227	431
Interest expense									(777)	(707)
Other financial income and expense[1]									39	(99)
Taxes, adjusted for above items (core taxes)									(2,056)	(2,001)
Core net income									**11,391**	**11,314**
Core net income attributable to shareholders of Novartis AG									**11,391**	**11,307**
Core basic EPS ($)[2]									**4.86**	**4.75**

(1) Adjusted for charges of $0.3 billion in 2016 related mainly to devaluation losses in Venezuela.

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

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2016 AND 2015 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS

	Innovative Medicines[1]		Sandoz		Alcon		Corporate		Group	
	2016	2015 restated[2]	2016	2015 restated[2]	2016	2015 restated[2]	2016	2015	2016	2015
	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m	$ m
IFRS Operating income from continuing operations	**7,426**	**7,815**	**1,445**	**1,300**	**(132)**	**281**	**(471)**	**(419)**	**8,268**	**8,977**
Amortization of intangible assets	**2,440**	**2,367**	**460**	**447**	**901**	**895**			**3,801**	**3,709**
Impairments										
Intangible assets	522	138	65	27	4	1			591	166
Property, plant & equipment related to the Group-wide rationalization of manufacturing sites	1	6	(7)	83					(6)	89
Other property, plant & equipment	76	(45)	8	14		1		21	84	(9)
Financial assets	18	32					99	91	117	123
Total impairment charges	**617**	**131**	**66**	**124**	**4**	**2**	**99**	**112**	**786**	**369**
Acquisition or divestment of businesses and related items										
Income	(68)	(22)		(1)			(229)	(260)	(297)	(283)
Expense	41	214		1			223	250	264	465
Total acquisition or divestment of businesses and related items, net	**(27)**	**192**		**0**			**(6)**	**(10)**	**(33)**	**182**
Other items										
Divestment gains	(608)	(626)	(6)				(48)	(54)	(662)	(680)
Restructuring items										
Income	(41)	(30)	(23)		(4)	(4)	(5)	(5)	(73)	(39)
Expense	418	422	123	121	33	29	65	57	639	629
Legal-related items										
Income	(99)								(99)	
Expense	205	578		40		4		(30)	205	592
Additional income	(61)	(119)		(2)	(13)	(5)	(22)	(68)	(96)	(194)
Additional expense	84	132	6	15	61	33	100	65	251	245
Total other items	**(102)**	**357**	**100**	**174**	**77**	**57**	**90**	**(35)**	**165**	**553**
Total adjustments	**2,928**	**3,047**	**626**	**745**	**982**	**954**	**183**	**67**	**4,719**	**4,813**
Core operating income from continuing operations	**10,354**	**10,862**	**2,071**	**2,045**	**850**	**1,235**	**(288)**	**(352)**	**12,987**	**13,790**
as % of net sales	*31.8%*	*32.6%*	*20.4%*	*20.3%*	*14.6%*	*20.6%*			*26.8%*	*27.9%*
Income from associated companies			6	2			697	264	703	266
Core adjustments to income from associated companies, net of tax							431	715	431	715
Interest expense									(707)	(655)
Other financial income and expense[3]									(99)	(24)
Taxes, adjusted for above items (core taxes)									(2,001)	(2,051)
Core net income from continuing operations									**11,314**	**12,041**
Core net loss from discontinued operations[4]										(256)
Core net income									**11,314**	**11,785**

Core net income attributable to shareholders of Novartis AG	**11,307**	**11,774**
Core basic EPS from continuing operations ($)[5]	**4.75**	**5.01**
Core basic EPS from discontinued operations ($)[5]		(0.11)
Total Core basic EPS ($)[5]	**4.75**	**4.90**

(1) Formerly named the Pharmaceuticals Division.

(2) Restated to reflect the new divisional structures and product transfers between divisions, announced on January 27, 2016.

(3) Adjusted for charges of $0.3 billion related mainly to Venezuela subsidiaries (2015: $0.4 billion).

(4) For details on 2015 discontinued operations reconciliation from IFRS to core net income, please refer to " 2015 Reconciliation of IFRS Results to Core Results Group Discontinued Operations".

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

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2017, 2016 AND 2015 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS GROUP

2017	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment of businesses and related items[3]	Other items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**32,960**	**3,401**	**92**		**125**	**36,578**
Operating income	**8,629**	**3,598**	**1,092**	**45**	**(514)**	**12,850**
Income before taxes	**8,999**	**3,974**	**1,093**	**45**	**(664)**	**13,447**
Taxes[5]	(1,296)					(2,056)
Net income	**7,703**					**11,391**
Basic EPS ($)[6]	**3.28**					**4.86**
The following are adjustments to arrive at Core Gross Profit						
Cost of goods sold	(17,175)	3,401	92		125	(13,557)
The following are adjustments to arrive at Core Operating Income						
Marketing & Sales	(12,861)				(4)	(12,865)
Research & Development	(8,972)	197	680		(218)	(8,313)
General & Administration	(2,136)				1	(2,135)
Other income	1,969		(9)	(117)	(1,065)	778
Other expense	(2,331)		329	162	647	(1,193)
The following are adjustments to arrive at Core Income before taxes						
Income from associated companies	1,108	376	1		(150)	1,335

(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 $376 million for the Novartis share of the estimated Roche core items.

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

(3) Acquisition or divestment of businesses and related items, including restructuring and integration charges: Other income and Other expense include transitional service-fee income and expenses and other items related to the portfolio transformation.

(4) Other items: Cost of goods sold, Other Income and Other expense include net restructuring and other charges related to the Group-wide rationalization of manufacturing sites; Cost of goods sold, Research & Development, General & Administration, Other income and Other expense include other restructuring income and charges and related items; Marketing & Sales includes an income from the release of a provision; Research & Development includes fair value adjustments to contingent consideration liabilities; Other income and Other expense include legal-related items; Other income also includes a gain from a Swiss pension plan amendment, product and financial asset divestment gains, a partial reversal of a prior period charge, an income from a settlement of a contract dispute and a fair value adjustment to contingent consideration sales milestone receivables; Other expense also

includes a provision for contract termination costs, a charge for onerous contracts and an amendment to the Swiss Pension Plan; Income from associated companies includes an adjustment of $150 million for the Novartis share of the estimated GSK Consumer Healthcare Holdings Ltd. core items.

(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 other items, although this is not always the case for

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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 $4.4 billion to arrive at the core results before tax amounts to $760 million. The average tax rate on the adjustments is 17.1%.

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

2016	IFRS results	Amortization of intangible assets[1]	Impairments[2]	Acquisition or divestment of businesses and related items[3]	Other items[4]	Core results
	$ m	$ m	$ m	$ m	$ m	$ m
Gross profit	**31,916**	**3,758**	**96**		**36**	**35,806**
Operating income	**8,268**	**3,801**	**786**	**(33)**	**165**	**12,987**
Income before taxes	**7,817**	**4,097**	**786**	**(33)**	**648**	**13,315**
Taxes[5]	(1,119)					(2,001)
Net income	**6,698**					**11,314**
Basic EPS ($)[6]	**2.82**					**4.75**