NOVARTIS AG
Form 20-F
January 25, 2017

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**As filed with the Securities and Exchange Commission on January 25, 2017**

# 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, 2016

OR

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

OR

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

**Commission file number 1-15024**

# NOVARTIS AG

*(Exact name of Registrant as specified in its charter)*

## NOVARTIS Inc.

*(Translation of Registrant's name into English)*

## Switzerland

*(Jurisdiction of incorporation or organization)*

**Lichtstrasse 35**
**4056 Basel, Switzerland**

*(Address of principal executive offices)*

Felix R. Ehrat
Group General Counsel

Novartis AG

CH-4056 Basel
Switzerland
Tel.: 011-41-61-324-1111
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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:

**2,374,059,013 shares**

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

**Yes ý No o**

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

**Yes o No ý**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

**Yes ý No o**

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ý Accelerated filer o Non-accelerated filer o

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

o U.S. GAAP ý International Financial Reporting Standards as issued by the International Accounting Standards Board o Other
If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow.

**Item 17 o Item 18 o**

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

**Yes o No ý**

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

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## INTRODUCTION AND USE OF CERTAIN TERMS

Novartis AG and its consolidated affiliates publish consolidated financial statements expressed in US dollars. Our consolidated financial statements 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 2016" included as Exhibit 99.1 to Form 6-K furnished to the SEC on January 25, 2017. Therefore the information in this Form 20-F should be read in conjunction with the "Excerpts from Novartis Annual Report 2016," as furnished to the SEC on Form 6-K on January 25, 2017. References to content not contained within the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, 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. No Group company operates the business of another Group company. Each executive identified in this Form 20-F reports directly to other executives of the Group company which employs the executive, or to that Group company's board of directors.

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

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

## FORWARD-LOOKING STATEMENTS

This Form 20-F contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Other written materials filed with or furnished to the US Securities and Exchange Commission (SEC) by Novartis, as well as other written and oral statements made to the public, may also contain forward-looking statements. Forward-looking statements can be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," or similar terms, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; potential shareholder returns or credit ratings; or regarding the potential outcome of the announced review of options 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 the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions

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with GSK, Lilly and CSL; 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 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. Nor can there be any guarantee that the review of options being undertaken to maximize shareholder value of the Alcon Division will reach any particular results, or at any particular time. Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL. 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, management's expectations could be affected by, among other things:

- regulatory actions or delays or government regulation generally;
- the potential that the strategic benefits, synergies or opportunities expected from the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL may not be realized or may take longer to realize than expected;
- the inherent uncertainties involved in predicting shareholder returns or credit ratings;
- the uncertainties inherent in 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;
- global trends toward health care cost containment, including ongoing pricing and reimbursement pressures, such as from increased publicity on pharmaceuticals pricing, including in certain large markets;
- 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;

general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries;

uncertainties regarding future global exchange rates;

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, 2016, 2015 and 2014, are included under "Novartis Group consolidated financial statements" on pages 178 to 247 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, and in "Item 18. Financial Statements" in this Form 20 F.

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

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2016** | **2015** | **2014** | **2013** | **2012** |
| | **($ millions, except per share information)** | | | | |
| **INCOME STATEMENT DATA** | | | | | |
| **Net sales to third parties from continuing operations** | **48,518** | **49,414** | **52,180** | **51,869** | **51,080** |
| **Operating income from continuing operations** | **8,268** | **8,977** | **11,089** | **10,983** | **11,507** |
| Income from associated companies | 703 | 266 | 1,918 | 599 | 549 |
| Interest expense | (707) | (655) | (704) | (683) | (724) |
| Other financial income and expense | (447) | (454) | (31) | (92) | (96) |
| **Income before taxes from continuing operations** | **7,817** | **8,134** | **12,272** | **10,807** | **11,236** |
| Taxes | (1,119) | (1,106) | (1,545) | (1,498) | (1,706) |
| **Net income from continuing operations** | **6,698** | **7,028** | **10,727** | **9,309** | **9,530** |
| Net income/(loss) from discontinued operations | | 10,766 | (447) | (17) | (147) |
| **Group net income** | **6,698** | **17,794** | **10,280** | **9,292** | **9,383** |
| Attributable to: | | | | | |
| Shareholders of Novartis AG | 6,712 | 17,783 | 10,210 | 9,175 | 9,270 |
| Non-controlling interests | (14) | 11 | 70 | 117 | 113 |
| **Basic earnings per share ($)** | | | | | |
| Continuing operations | 2.82 | 2.92 | 4.39 | 3.76 | 3.89 |
| Discontinued operations | | 4.48 | (0.18) | 0.00 | (0.06) |
| Total | 2.82 | 7.40 | 4.21 | 3.76 | 3.83 |
| **Diluted earnings per share ($)** | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Continuing operations | 2.80 | 2.88 | 4.31 | 3.70 | 3.85 |
| Discontinued operations | | 4.41 | (0.18) | 0.00 | (0.06) |
| Total | 2.80 | 7.29 | 4.13 | 3.70 | 3.79 |
| Cash dividends[1] | 6,475 | 6,643 | 6,810 | 6,100 | 6,030 |
| Cash dividends per share in CHF[2] | 2.75 | 2.70 | 2.60 | 2.45 | 2.30 |

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

(2) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2012 through 2015 were approved at the respective AGMs and dividends for 2016 will be proposed to the Annual General Meeting on February 28, 2017 for approval.

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| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2016 | 2015 | 2014 | 2013 | 2012 |
| | | | ($ millions) | | |
| **BALANCE SHEET DATA** | | | | | |
| Cash, cash equivalents and marketable securities & derivative financial instruments. | 7,777 | 5,447 | 13,862 | 9,222 | 8,119 |
| Inventories | 6,255 | 6,226 | 6,093 | 7,267 | 6,744 |
| Other current assets | 10,899 | 11,172 | 10,805 | 13,294 | 13,141 |
| Non-current assets | 105,193 | 108,711 | 87,826 | 95,712 | 96,187 |
| Assets related to discontinued operations | | | 6,801 | 759 | |
| **Total assets** | **130,124** | **131,556** | **125,387** | **126,254** | **124,191** |
| Trade accounts payable | 4,873 | 5,668 | 5,419 | 6,148 | 5,593 |
| Other current liabilities | 17,336 | 18,040 | 19,136 | 20,170 | 18,458 |
| Non-current liabilities | 33,024 | 30,726 | 27,570 | 25,414 | 30,877 |
| Liabilities related to discontinued operations | | | 2,418 | 50 | |
| **Total liabilities** | **55,233** | **54,434** | **54,543** | **51,782** | **54,928** |
| Issued share capital and reserves attributable to shareholders of Novartis AG | 74,832 | 77,046 | 70,766 | 74,343 | 69,137 |
| Non-controlling interests | 59 | 76 | 78 | 129 | 126 |
| **Total equity** | **74,891** | **77,122** | **70,844** | **74,472** | **69,263** |
| **Total liabilities and equity** | **130,124** | **131,556** | **125,387** | **126,254** | **124,191** |
| Net assets | 74,891 | 77,122 | 70,844 | 74,472 | 69,263 |
| Outstanding share capital | 896 | 890 | 898 | 912 | 909 |
| Total outstanding shares (millions) | 2,374 | 2,374 | 2,399 | 2,426 | 2,421 |

**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 ($) |
|---|---|---|---|
| 2012 | March 2013 | 2.30 | 2.44 |
| 2013 | March 2014 | 2.45 | 2.76 |
| 2014 | March 2015 | 2.60 | 2.67 |
| 2015 | March 2016 | 2.70 | 2.70 |
| 2016[1] | March 2017 | 2.75 | 2.69[2] |

(1) Dividend to be proposed at the Annual General Meeting on February 28, 2017 and to be distributed March 6, 2017

(2) Translated into US dollars at the December 31, 2016 rate of $0.978 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 17, 2017, as found on Bloomberg Market System, was CHF 1.00 = $0.99.

| **Year ended December 31, ($ per CHF)** | **Period End** | **Average[1]** | **Low[2]** | **High[2]** |
|---|---|---|---|---|
| 2012 | 1.09 | 1.07 | 1.02 | 1.12 |
| 2013 | 1.12 | 1.08 | 1.05 | 1.12 |
| 2014 | 1.01 | 1.09 | 1.01 | 1.13 |
| 2015 | 1.01 | 1.04 | 0.97 | 1.08 |
| 2016 | 0.98 | 1.01 | 0.98 | 1.04 |
| **Month** | | | | |
| August 2016 | | | 1.02 | 1.05 |
| September 2016 | | | 1.02 | 1.04 |
| October 2016 | | | 1.01 | 1.03 |
| November 2016 | | | 0.98 | 1.03 |
| December 2016 | | | 0.97 | 0.99 |
| January 2017 (through January 17, 2017) | | | 0.97 | 0.99 |

(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 and Alcon Divisions, as well as certain products of our Sandoz Division, 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. 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 medicine typically results in a significant and rapid reduction in net sales and net income for the patented product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other

intellectual property rights. Such competition can also result from the entry of generic versions of another medicine in the same therapeutic class as

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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 patents, including conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement, before final resolution of legal proceedings.

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

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

We faced generic competition in the US, Japan and some EU countries for our best-selling product *Gleevec/Glivec* during most of 2016. In the remaining EU countries, certain of our *Glivec* intellectual property rights expired in December 2016, and generic competition there has begun.

Patent protection for our *Sandostatin* products has expired. Generic versions of *Sandostatin* SC are available in the US, EU and Japan. 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.

*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 and Japan, and *Exforge HCT*, which is not marketed in Japan, has generic competition in the US. Generic competition for *Exforge* began in some countries in Europe in January 2017.

Certain intellectual property protecting our major products *Afinitor* and *Gilenya* will expire in 2018, 2019 and 2020. In addition, some of the patents protecting these products are being challenged in the US, raising the possibility of an earlier entry of generic competition.

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 2017, we expect an impact on our net sales of about $2.5 billion as a result of the loss of intellectual property protection for our products, including *Gleevec/Glivec*. Because we typically have substantially reduced marketing and research and development expenses related to products that are in their final year of exclusivity, we expect that this loss of intellectual property protection also will have an impact on our 2017 operating income in an amount corresponding to a significant portion of the products' lost sales. The magnitude of the impact of generic competition could depend on a number of factors, including the time of year at which such exclusivity would be lost; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic competitor products approved, including whether, in the US, a single competitor is granted an exclusive marketing period, and whether an authorized generic is launched; and the geographies in which generic competitor products are approved, including the strength of the market for generic pharmaceutical products in such geographies and the comparative profitability of branded pharmaceutical products in such geographies.

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

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***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 certain key products, known as our Growth Products. We consider our Growth Products to be an indicator of the rejuvenation of our portfolio of products. Growth Products consist of 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). In 2016, our Growth Products contributed $17.1 billion, or 35% of our total net sales.

If these products or any of our other 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.

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

Products that compete with ours, including products competing against our Growth Products or other major products, are launched from time to time. We cannot predict with accuracy the timing of the introduction of such competitive products or their possible effect on our sales. However, products significantly competitive to our major products *Cosentyx, Lucentis, Gilenya* and *Afinitor* have been launched. Such products, and other competitive products, could significantly affect the revenue from our products and our results of operations. In addition, the impact on our results of operations could be compounded to the extent such competition results in us making significant additional investments in marketing and sales.

Similarly, our Alcon Division, a leader in the eye care industry, has suffered declining sales and profits due in part to increased competition for its products. To counter this, we are continuing efforts to improve the division's revenues and profits. Our efforts under this plan are expected to take time to succeed. As a result, such competition and the costs of our efforts to improve Alcon's performance, as well as other factors, can be expected to affect Alcon's business, financial condition or results of operations in the near term. In addition, despite the devotion of significant resources to our efforts to improve Alcon's performance, those efforts may prove insufficient. Should our efforts fail to accomplish their goals, or fail to do so in a timely manner, it could have a material adverse impact on our business, financial condition or results of operations beyond the near term, as well. See also the discussion of Alcon's new product development efforts in " Our research and development efforts may not succeed in bringing new products to market, or may fail to do so cost efficiently enough, or in a manner sufficient to grow our business, replace lost revenue and income and take advantage of new technologies," below, and the discussion of the impact of competition on our Sandoz Division in " Failure to obtain marketing exclusivity periods for new generic products, or to develop biosimilars and other differentiated products, as well as intense competition from patented and generic pharmaceuticals companies, may have an adverse effect on the success of our Sandoz Division," 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, and are reimbursed by payors. 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. Developing new healthcare products and bringing them to market, however, is a highly costly, lengthy and uncertain process. In spite of our significant investments, there can be no guarantee that our research and development activities will produce commercially viable new products that will enable us to 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 strategic transactions or reorganizations," below, with regard to our recent reorganization of our pharmaceutical product development organization.

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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 will be for us to recoup our research and development costs. New products must undergo intensive preclinical and clinical testing, and must be approved by means of highly complex, lengthy and expensive approval processes which can vary from country to country. During each stage, there is a substantial risk that we will encounter serious obstacles that will further delay us and add substantial expense, that we will develop a product with limited potential for commercial success, or that we will be forced to abandon a product in which we have invested substantial amounts of time and money. These risks may include failure of the product candidate in preclinical studies, difficulty enrolling patients in clinical trials, clinical trial holds or other delays in completing clinical trials, delays in completing formulation and other testing and work necessary to support an application for regulatory approval, adverse reactions to the product candidate or other safety concerns, insufficient clinical trial data to support the safety or efficacy of the product candidate 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 a series of widely publicized issues, health regulators have increased their focus on product safety. Governmental authorities and payors around the world have also paid increased attention to whether new products offer a significant benefit over other products in the same therapeutic class. These developments have led to requests for more clinical trial data, for the inclusion of significantly higher numbers of patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has become even more challenging.

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.

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

Our Alcon Division faces similar challenges in developing new products and bringing them to market. Alcon's Surgical and Vision Care products face medical device development and approval processes that are often similarly difficult. Alcon is taking steps to increase its innovation power and the success of its research and development efforts. But this can be expected to be costly and to require extensive efforts over time. There can be no certainty that Alcon will be successful in these efforts, in either the short- or the long-term, and if Alcon is not successful, there could be a material adverse effect on the success of the Alcon Division, and on the Group as a whole. See also the discussion of Alcon in " Our products face important patent expirations and significant competition" above.

In addition, our Sandoz Division has made, and expects to continue to make, significant investments in the development of differentiated, "difficult-to-make" generic products, including biotechnology-based, "biologic" medicines intended for sale as bioequivalent or "biosimilar" generic versions of currently-marketed biotechnology products. While the development of such products typically is significantly less costly and complex than the development of the equivalent originator medicines, it is nonetheless often significantly more costly and complex than those for non-differentiated generic products. In addition, despite significant efforts by us and others, to date 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

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adverse effect on the long-term success of the Sandoz Division and the Group as a whole. See also " Failure to obtain marketing exclusivity periods for new generic products, or to develop biosimilars and other differentiated products, as well as intense competition from patented and generic pharmaceuticals companies, may have an adverse effect on the success of our Sandoz Division," 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, Good Clinical Practices requirements, data integrity requirements, the fair treatment of patients in developing countries, and animal welfare requirements. Should we fail to properly manage such issues, we risk injury to third parties, damage to our reputation, negative financial consequences as a result of potential claims for damages, sanctions and fines, and the potential that our investments in research and development activities could have no benefit to the Group.

If we are unable to cost-effectively maintain 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 persistently weak economic and financial environment in many countries and the increasing demand for healthcare resulting from the aging of the global population and associated increases in non-communicable diseases. 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. In addition, these pressures are augmented by intense publicity regarding the pricing of pharmaceuticals by our competitors, as well as government investigations and legal proceedings regarding pharmaceutical pricing practices.

As a result, even though the pharmaceutical industry's share of overall healthcare costs is comparatively low, 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, and growing pressure on physicians to reduce the prescribing of patented prescription medicines. For more information on such price controls see "Item 4. Information on the Company Item 4.B Business Overview 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 " The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results," below, with regard to the impact of economic conditions on our pricing.

We expect these challenges to continue and potentially to increase in 2017 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 proposals that we be required to disclose the methods that we use to set the prices for our products.

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. 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, and are increasingly challenging practices previously considered to be legal.

Such proceedings are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments 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 despite having potentially significant defenses against them, in order 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.

Our businesses are and have been subject to a number of these types of cases and governmental investigations. For example, in 2013, the US government filed a civil complaint in intervention to an individual *qui tam* action against our affiliate Novartis Pharmaceuticals Corporation (NPC) in the United States District Court for the Southern District of New York (SDNY) involving several of NPC's cardiovascular medications. The complaint, as subsequently amended, asserts federal False Claims Act and common law claims with respect to speaker programs and other promotional activities for certain NPC cardiovascular medications allegedly serving as mechanisms to provide kickbacks to healthcare professionals. It seeks unspecified damages, which according to the complaint are "substantial," including treble damages and maximum civil penalties per claim, as well as disgorgement of Novartis profits from the alleged unlawful conduct. In 2013, New York State filed a civil complaint in intervention asserting similar claims. The individual relator continues to litigate the kickback claims on behalf of other states and municipalities.

See also "Note 20. Provisions and other non-current liabilities" and "Note 28. Commitments and contingencies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on

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January 25, 2017 for information on other significant legal matters also are pending against us, and see " Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses" below.

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

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

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

The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. Whether our products are manufactured at our own dedicated manufacturing facilities or by third parties, we must ensure that all manufacturing processes comply with current Good Manufacturing Practices (cGMP) and other applicable regulations, as well as with our own high quality standards. In recent years, health authorities have substantially intensified their scrutiny of manufacturers' compliance with such requirements.

If we or our third-party suppliers fail to comply fully with these requirements and the health authorities' expectations, then we could be required to shut down our production facilities or production lines, or could be prevented from importing our products from one country to another. This could lead to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. 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 order to meet increasing health authority expectations and our own high quality standards, we are devoting substantial time and resources to remediate issues, improve quality and assure consistency of product supply at our manufacturing sites around the world. Ultimately, there can be no guarantee of the outcome of these efforts. Nor can there be any guarantee that we will not again face significant manufacturing issues, or that we will successfully manage such issues when they arise.

In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may rely on a single source of supply. Because of these complexities, we are required to plan our production activities well in advance. 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 increase production sufficiently 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 in the loss of the resources spent to produce it.

A significant portion of our portfolio are "biologic" products. Unlike traditional "small-molecule" drugs, biologic drugs or other biologic-based products cannot be manufactured synthetically, but typically must be produced from living plant or animal micro-organisms. As a result, the production of biologic-based products which meet all regulatory requirements is especially complex. Even slight deviations at any point in the production process may lead to production failures or recalls. In addition, because the production process is based on living plant or animal micro-organisms, the process could be affected by contaminants that could impact those micro-organisms. As a result, the inherent fragility of certain of our raw material supplies and production processes may cause the production of one or more of our products to be disrupted, potentially for extended periods of time.

We also manufacture and sell a number of sterile products, including oncology products, which are technically complex to manufacture, and require sophisticated environmental controls. Because the production

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process for such products is so complex and sensitive, the chance of production failures and lengthy supply interruptions is increased.

In addition, 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.

In sum, a disruption in the supply of certain key products whether as a result of a failure to comply with applicable regulations or health authority expectations, the fragility of the production process, inability to obtain product or raw materials from a sole source of supply, natural or man-made disasters at one of our facilities or at a critical supplier or vendor, or our failure to accurately predict demand could have a material adverse effect on our business, financial condition or results of operations, as well as our reputation. See also " We may not successfully achieve our goals in strategic 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, certain countries are or may experience periods of high inflation. This could lead these countries to devalue their currencies, and to set exchange controls, as, for example, Venezuela has done. Such steps taken by Venezuela have impacted our financial results. See " The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above. Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

Despite measures undertaken to reduce, or hedge against, foreign currency exchange risks, because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including 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 29. Financial Instruments Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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

As part of our strategy, from time to time we evaluate and pursue potential business acquisitions and divestitures to expand or complement our existing businesses, or to enable us to focus more sharply on our strategic businesses. We cannot ensure that suitable acquisition candidates will be identified. Acquisition activities can be thwarted by 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 integrate the business may not meet expectations, or may otherwise not be successful, as a result of differences in corporate culture, difficulties in retaining key personnel, customers and suppliers, difference in

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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.

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

In addition, as part of our strategy, from time to time we reassess the optimal organization of our business, including the allocation of products by division and the level of centralization and simplification of certain functions across the Group, to better align those products and functions with the capabilities and expertise required for competitive advantage. As an example of this, in May 2016, we announced changes to focus our former Pharmaceuticals Division by creating two business units: Novartis Pharmaceuticals and Novartis Oncology. These business units formed the Innovative Medicines Division of Novartis, reporting to the CEO of Novartis. Similarly, in January 2016 we announced a series of strategic actions intended to further focus our divisions, including focusing our Alcon Division on its Surgical and Vision Care franchises, strengthening our ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to our Innovative Medicines Division, and shifting selected mature pharmaceutical products from our Innovative Medicines Division into Sandoz. We also announced steps during the course of 2016 to increase Group-wide coordination of drug development, and to improve efficiency with an integrated manufacturing operation and more shared commercial and medical services at the country level. Similarly, in 2014 we created a shared services organization, Novartis Business Services (NBS). NBS consolidates a number of business support services previously spread across divisions, including Information Technology, Financial Reporting and Accounting Operations, Real Estate & Facility Services, Procurement, Payroll and Personnel Administration and the Innovative Medicines Global Business Services. We expect these actions to further strengthen our competitive position, enable us to maintain our leading position in research and development, and free resources for our growth priorities. But the expected benefits of these reorganizations may never be fully realized or may take longer to realize than expected. There can be no certainty that the numerous businesses and functions involved will be successfully integrated into the new organizations 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 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 breach the privacy rights of third parties.***

Our business is heavily dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes. In addition, Novartis and our employees rely on internet and social media tools and mobile technologies as a means of communications, and to gather information. We are also increasingly seeking to develop technology-based products such as mobile applications that go "beyond the pill" to improve patient welfare in a variety of ways, which could also result in us gathering information about patients and others electronically.

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

Any such events could negatively impact important business processes, such as the conduct of scientific research and clinical trials, the submission of the results of such efforts to health authorities in support of requests for product approvals, the functioning of our manufacturing and supply chain processes, our compliance with legal obligations and other key business activities. Such potential information technology issues could lead to the loss of important information such as trade secrets or other intellectual property and could accelerate the development or manufacturing of competing products by third parties. In addition, malfunctions in software or devices that make significant use of information technology, including our Alcon surgical equipment, could lead to a risk of harm to patients.

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

In addition, we use Internet, social media and mobile tools as a means to communicate with the public about our products or about the diseases our products are intended to treat. However, such uses risk the loss of trade secrets or other intellectual property. In addition, there continue 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 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 shareholders' litigation, which could require us to expend significant resources to continue to modify or enhance our protective measures and to remediate any damage. Such events could have a material adverse effect on our business, financial condition, results of operations and reputation.

***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 expected fair value of the goodwill and other intangible assets would be less than their carrying value on the Group's consolidated balance sheet at any point in time.

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets, investments in associated companies and goodwill, for impairment. Goodwill, acquired research and development, and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. Impairment testing under IFRS may lead to impairment charges in the future. Any significant

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impairment charges could have a material adverse effect on our results of operations and financial condition. In 2016, for example, we recorded intangible asset impairment charges of $591 million. 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 11. Goodwill and Intangible Assets Movements" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. In addition, we continue to see weak economic growth or a slowing of economic growth rates in certain emerging growth markets, such as China, Russia, Brazil and India. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve.

In particular, financial weakness in certain countries has increased pressures on those countries, and on payors in those countries, to force healthcare companies to decrease the prices at which we may sell them our products. See also "Item 4. Information on the Company Item 4.B Business Overview Innovative Medicines Price Controls." Concerns continue that payors and customers in some countries, including Greece, Italy, Portugal, Spain, Brazil, Russia and Saudi Arabia may not be able to pay us in a timely manner.

Certain other countries are experiencing high inflation rates and have taken steps to introduce exchange controls and limit companies from distributing retained earnings or paying intercompany payables due from those countries. The most significant country in this respect is Venezuela, where we are exposed to a potential devaluation loss in the income statement with our subsidiaries in the country. The Group's subsidiaries in Venezuela are experiencing a significant reduction in approvals for remittance of US dollars outside the country at the exchange rate available for imports of specific goods and services of national priority, including medicines and medical supplies. As a result, in November 2016, the Group changed the exchange rate applied to translate the financial statements of its Venezuelan subsidiaries to the floating rate of DICOM (Systema de Divisa Complementaria) which was VEF 658 per US dollar as of November 1, 2016. A corresponding $0.3 billion revaluation loss on the outstanding intercompany balances was recognized in the fourth quarter of 2016. Due to the recorded reserves against the intercompany balances, the net outstanding intercompany payable balance of Venezuela subsidiaries reduced to an insignificant amount as per December 31, 2016.

Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future. See also "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources Effects of Currency Fluctuations" and " Condensed Consolidated Balance Sheets," and "Note 15. Trade Receivables" and "Note 29. Financial Instruments Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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

In addition, the varying effects of difficult economic times on the economies, currencies and financial markets of different countries has impacted, and may continue to unpredictably impact, our business and results

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

To the extent that the economic and financial conditions directly affect consumers, some of our businesses, including the elective surgical 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 increasing requirements in certain countries that patients pay a larger contribution toward their own healthcare costs. As a result, there is a risk that consumers may cut back on prescription drugs and medical devices to help cope with rising costs and difficult economic times.

These issues may be further impacted by unpredictable political conditions currently existing in various parts of the world, including a backlash in certain areas against free trade, the ongoing refugee crisis, anti-immigrant sentiment, social unrest and fears of terrorism. In the US, opposition to free trade agreements was a significant issue in the recent presidential election. Similarly, uncertainties remain in Europe following the UK's "Brexit" vote and the rise of populist movements in various EU countries. And significant conflicts continue in parts of the Middle East and places such as Ukraine.

Collectively, such difficult conditions can, among other things, interfere with free trade in goods, increase the costs and difficulties of international transactions and potentially disturb the international flow of goods, and thus 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.

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

Similarly, increased scrutiny of corporate taxes and executive pay may lead to significant business disruptions or other adverse business conditions, and may interfere with our ability to attract and retain qualified personnel. See " Changes in tax laws or their application could adversely affect our results of operation" and " An inability to attract and retain qualified personnel could adversely affect our business" below.

***Our indebtedness could adversely affect our operations.***

As of December 31, 2016 we had $17.9 billion of non-current financial debt and $5.9 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 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 invest a significant amount of effort and resources into outsourcing the performance of certain key business functions to third parties, including research and development collaborations, manufacturing operations, warehousing, distribution activities, certain finance functions, marketing activities, data management and others. Our reliance on outsourcing and third parties for certain functions, such as the research and development or manufacturing of products, may limit the potential profitability of such products. In addition, despite contractual relationships with the third parties to whom we outsource these functions, we cannot ultimately control how they perform their contracts. Nonetheless, we depend on these third parties to achieve results which may be significant

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to us. If the third parties fail to meet their obligations or to comply with the law, we may lose our investment in the collaborations and fail to receive the expected benefits. In addition, should any of these third parties fail to comply with the law in the course of their performance of services for us, there is a risk that we could be held responsible for such violations of law, as well, and that our reputation may suffer. Any such failures by third parties could have a material adverse effect on our business, financial condition, results of operations or reputation.

In particular, in many countries, including many developing markets, we rely heavily on third party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to those within our organization. Some of these countries are plagued by corruption. If our efforts to detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties with applicable laws and regulations, which may have a material adverse effect on our reputation and on our business, financial condition or results of operations.

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

At a time of slowing growth in sales of healthcare products in industrialized countries, many emerging markets have in recent years experienced proportionately higher sales growth and an increasing contribution to the industry's global performance. In 2016, our Continuing Operations generated $11.9 billion, or approximately 25% (2015: 25%) of our net sales from Emerging Growth Markets which comprise all markets other than the Established Markets of the US, Canada, Western Europe, Japan, Australia and New Zealand as compared with $36.6 billion, or approximately 75% (2015: 75%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 4% in constant currencies in 2016, compared to 1% sales growth in constant currencies in the Established Markets during the same period. As a result of this trend, we continue to take steps to increase our activities in the Emerging Growth Markets, and have been making significant investments in our businesses in those countries.

In the past two years, however, certain of these Emerging Growth Market countries, including Brazil, India, China and Russia, have experienced economic slowdowns. As a result, there can be no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will once again experience growth rates significantly in excess of the world's largest markets. In particular, some Emerging Growth Market countries may be especially vulnerable to the effects of the persistently weak global financial environment, may have very limited resources to spend on healthcare or may be susceptible to political and social instability. See " The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above. Many of these countries are subject to increasing political and social pressures, including from a growing middle class seeking increased access to healthcare. Such pressures on local government may in turn result in an increased focus by the governments on our pricing, and may put at risk our intellectual property. See " Our business is increasingly affected by pressures on pricing for our products," and "Our products face important patent expirations and significant competition" above.

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

In addition, many of these countries have currencies that may fluctuate substantially. If these currencies devalue significantly against the US dollar and we cannot offset the devaluations with price increases, then our products may become less profitable, or may otherwise impact our reported financial results. Currency devaluation risk may also exist in countries with high inflation economies. Should these countries take steps that cause their currencies to be devalued, we may realize a significant financial loss. See " The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" and " Foreign exchange fluctuations may adversely affect our

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earnings and the value of some of our assets," above. Ongoing conditions in such high inflation countries could lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

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

***Failure to obtain marketing exclusivity periods for new generic products, or to develop biosimilars and other differentiated products, as well as intense competition from patented and generic pharmaceuticals companies, may have an adverse effect on the success of our Sandoz Division.***

Our Sandoz Division achieves significant revenue opportunities when it secures and maintains exclusivity periods granted for generic products in certain markets particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act for first-to-file generics and when it is able to develop biosimilars and other differentiated products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz.

In addition, the division faces intense competition both from companies that market patented pharmaceutical products, which sometimes take aggressive steps to prevent or delay the introduction of generic medicines, to limit the availability of exclusivity periods or to reduce their value, and from other generic pharmaceuticals companies, which aggressively compete for exclusivity periods and for market share of generic products that may be identical to certain of our generic products. These activities may increase the costs and risks associated with our efforts to introduce generic products, may further limit the prices at which we are able to sell these products, and may delay or entirely prevent their introduction. See also " 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.

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, despite ongoing efforts by us and others to encourage the development of such regulations, such regulations do not ultimately favor the development and sale of biosimilar products, then we may fail to achieve expected returns on the investments by Sandoz in the development of biosimilars. See also " Our research and development efforts may not succeed in bringing new products to market, or may fail to do so cost-efficiently enough, or in a manner sufficient to grow our business and replace lost revenue and income" above, with regard to the risks involved in our efforts to develop differentiated generic products.

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

We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. While most of our plans are now defined contribution plans, certain of our associates remain under defined benefits plans. For these defined benefits plans, we are required to make significant assumptions and estimates about future events in calculating the present value of expected future 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 (including the effects of the persistently weak global financial environment, which, to date, have resulted in extremely low or negative interest rates in many countries), higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the interest rate we apply in determining the present value of expected future defined benefit obligations of one-quarter of one percent would have increased our year-end defined benefit pension obligation for plans in Switzerland, US, UK, Germany and Japan, which represent about 95% of the Group total defined benefit pension obligation, by $0.8 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. Further, additional employer contributions might be required if plan funding falls below the levels required by local rules. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see

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"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 25. Post-Employment Benefits for Associates" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017. See also "  The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above.

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

Our worldwide operations are taxed under laws in the jurisdictions in which we operate. However, the integrated nature of our worldwide operations can produce conflicting claims from revenue authorities as to the determination of profits to be taxed in individual countries. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the incidence of double taxation on our revenues and capital gains. But 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 the Anti Tax Avoidance Directive and continues to extend the application of the fiscal state aid policy and respective investigation on tax ruling practices. These tax reform initiatives on the OECD and European levels also need local country implementation, including in our home country of Switzerland, which may result in significant changes to established tax principles and could lead to an increased risk of international tax disputes.

Although we have taken steps to be in compliance with the evolving OECD and European tax initiatives, and will continue to do so, significant uncertainties remain as to the outcome of the Swiss and other countries' tax reform efforts. Such 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, could require us to adapt our tax structure, increase our effective tax rate and adversely affect our financial results.

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

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can potentially be life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could 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 16%, 12% and 6%, respectively, of Group net sales in 2016. The largest trade receivables outstanding were for these three customers, amounting to 14%, 9% and 6%, respectively, of the Group's trade receivables at December 31, 2016. 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 substantial loss of sales and an inability to collect amounts owed to us. This could have a material adverse effect on our business, financial condition and results of operations.

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

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

Future economic growth will demand talented associates and leaders, yet the market for talent has become increasingly competitive. In particular, emerging markets are expected to continue to be a driving force in global growth, but in countries like Russia and China there is a limited pool of executives with the training and international experience needed to work successfully in a global organization like Novartis.

In addition, shifting demographic trends are expected to result in fewer students, fewer graduates and fewer people entering the workforce in the Western world in the next 10 years. Moreover, many members of younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles.

The supply of talent for certain key functional and leadership positions is decreasing, and a talent gap is visible for some professions and geographies engineers in Germany, for example. Recruitment is increasingly regional or global in specialized fields such as clinical development, biosciences, chemistry and information technology. In addition, the geographic mobility of talent is expected to decrease in the future, with talented individuals in developed and emerging countries anticipating ample career opportunities closer to home than in the past. This decrease in mobility may be worsened by anti-immigrant sentiments in many countries, and laws discouraging immigration.

In addition, our ability to hire qualified personnel also depends on the flexibility to reward superior performance and to pay competitive compensation. Laws and regulations on executive compensation, 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.D Property, Plants and Equipment Environmental Matters" and "Note 20. Provisions and other non-current liabilities" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

***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

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

**Risks Related To Our ADRs**

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

Our American Depositary Shares (ADSs) each representing one Novartis share and evidenced by American Depositary Receipts (ADRs) trade on the NYSE in US dollars. Since the shares underlying the ADRs are listed in Switzerland on the SIX Swiss Exchange (SIX) and trade in Swiss francs, the value of the ADRs may be affected by fluctuations in the US dollar/Swiss franc exchange rate. In addition, since dividends that we may declare will be denominated in Swiss francs, exchange rate fluctuations will affect the US dollar equivalent of dividends received by holders of ADRs. If the value of the Swiss franc 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 32. Principal Group Subsidiaries and Associated Companies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**Important Corporate Developments 2014-January 2017**

***2017***

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. The review will be conducted during the course of 2017 and in a manner such that Alcon Division associates can fully focus on the unit's return to growth. The ophthalmic pharmaceutical portfolio is now fully integrated into our Innovative Medicines Division and will not be part of the review.

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 is subject to customary closing conditions, including regulatory approval.

***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. Upon exercise of the option, Novartis will obtain an exclusive, worldwide license to develop and commercialize products containing emricasan. The exercise of the option is subject to customary closing conditions, including regulatory approval.

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.

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| November | Novartis announces that it has acquired Selexys Pharmaceuticals Corporation and SEG101 (crizanlizumab, formerly SelG1) 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 Executive Committee of Novartis (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. |
| | 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***

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| 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 |

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| | 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. |

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| July | Novartis announces a swap of three mid-stage clinical assets for equity and a share of milestones and royalties on future commercial sales with Mereo BioPharma Group Limited. |
| June | Novartis announces that it has entered into an agreement to acquire Spinifex Pharmaceuticals, Inc., a US and Australian-based, privately held development stage company focused on developing a peripheral approach to treat neuropathic pain such as EMA401, a novel angiotensin II Type 2 receptor (AT2R) antagonist. This acquisition was completed on July 24, 2015. |
| March | Novartis announces entry into an alliance with Aduro Biotech focused on discovery and development of next-generation cancer immunotherapies targeting the STING signaling pathway, and the launch of a new immuno-oncology research group. |
| February | Novartis completes a CHF 1.375 billion bond offering listed on the SIX Swiss Exchange. |

***2014***

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| October | Novartis announces a definitive agreement with CSL of Australia to divest its influenza vaccines business for $275 million. This divestment was completed effective July 31, 2015. |
| | Novartis announces changes to the Novartis Executive Committee. Three members of the Executive Committee of Novartis, George Gunn, Brian MacNamara and Andrin Oswald, would leave the Company following the completion of the relevant portfolio transactions announced in April 2014. |
| | Novartis announces that it has entered into a collaboration with Bristol-Myers Squibb Company to evaluate three molecularly targeted compounds in combination with Bristol-Myers Squibb's investigational PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab), in Phase I/II trials of patients with non-small cell lung cancer. |
| August | Novartis appoints a Chief Ethics, Compliance and Policy Officer reporting directly to the CEO. |
| July | Novartis announces that its Alcon Division has entered into an agreement with a division of Google Inc., to in-license its "smart lens" technology for all ocular medical uses. |
| June | Novartis announces that the FDA licensed its manufacturing facility in Holly Springs, North Carolina for the commercial production of cell-culture influenza vaccines, with the capacity to significantly increase production in the event of an influenza pandemic. |
| May | Novartis enters into a licensing and commercialization agreement with Ophthotech Corporation for the exclusive rights to market pegpleranib outside the US. In November 2015, Genentech entered into an agreement with Novartis to participate in certain financial rights related to the Novartis licensing and commercialization agreement with Ophthotech Corporation for pegpleranib. |
| April | Novartis announces a set of definitive inter-conditional agreements with GSK. Under these agreements, Novartis would acquire GSK oncology products and certain related assets, would be granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline (excluding oncology vaccines) and would divest the Vaccines Division (excluding its influenza vaccines business) to GSK. The two companies would also create a joint venture in consumer healthcare, of which Novartis would own 36.5%. These transactions were completed on March 2, 2015. |
| | Novartis also announces a definitive agreement with Lilly to divest the Company's Animal Health Division. This divestment was completed on January 1, 2015. |
| | Novartis announces the creation of a shared services organization, Novartis Business Services (NBS). NBS consolidates a number of business support services previously spread across divisions, including Information Technology, Financial Reporting and Accounting Operations, Real Estate & Facility Services, Procurement, Payroll and Personnel Administration and the Pharmaceuticals Global Business Services. This reorganization was designed to improve profitability and free up resources that could be reinvested in growth and innovation, and to allow our divisions to focus more on customer-facing activities. NBS became effective on July 1, 2014. |
| February | Novartis announces the acquisition of CoStim Pharmaceuticals Inc., a Cambridge, Massachusetts-based, privately held biotechnology company focused on cancer immunotherapy. The acquisition brings to Novartis late discovery stage immunotherapy programs directed to several targets, including PD-1. |

Novartis appoints a Global Head, Corporate Responsibility reporting directly to the CEO.

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January Novartis implements several changes to its governance structure. These include elimination of the Chairman's Committee of the Novartis AG Board of Directors; transfer of operational responsibilities that previously rested with the Chairman or the Chairman's Committee, such as approval authority for management compensation, to the CEO or the Executive Committee; and establishment of the Research and Development Committee of the Novartis AG Board of Directors to oversee Novartis research and development strategy and advise the Board on scientific trends and activities.

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." For more information on the transactions with GSK, Lilly or CSL, see "Item 4.B Business Overview Overview" and "Item 10.C Material Contracts."

**4.B Business Overview**

**OVERVIEW**

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio includes innovative 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, 2105 to CSL and our Animal Health Division was sold on January 1, 2015 to Lilly. For more detail on certain of these transactions see, "Item 10.C Material Contracts."

Continuing Operations:

- Innovative Medicines (formerly named Pharmaceuticals): Innovative patent-protected prescription medicines
- Sandoz: Generic pharmaceuticals and biosimilars
- 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

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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.

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 and Novartis Business Services.

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, which supports our Innovative Medicines Division and also collaborates with our Sandoz Division. More than 6,000 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, Singapore and China. For more information about NIBR, see " Innovative Medicines Research and Development Research program," below.

Effective February 1, 2016, Mike Ball was appointed Division Head and CEO Alcon, and as a member of the Executive Committee of Novartis (ECN). Mike Ball succeeded Jeff George, who decided to leave Novartis.

Effective April 1, 2016, Alcon's Ophthalmic Pharmaceuticals products were transferred to our Innovative Medicines Division. At the same time, selected mature, non-promoted pharmaceutical products were shifted from our Innovative Medicines Division to Sandoz, which has proven experience in managing mature products successfully. Following these changes our Alcon Division is now focused on its Surgical and Vision Care franchises.

In January 2017, we announced that we are 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. The review will be conducted during the course of 2017 and in a manner such that Alcon Division associates can fully focus on the unit's return to growth. The ophthalmic pharmaceutical portfolio is now fully integrated into our Innovative Medicines Division and will not be part of the review.

In May 2016, Novartis announced changes to focus its former Pharmaceuticals Division by creating two business units, Novartis Pharmaceuticals and Novartis Oncology, to form the Innovative Medicines Division. Effective July 1, 2016, Paul Hudson was appointed CEO, Novartis Pharmaceuticals and Bruno Strigini was appointed CEO, Novartis Oncology, both as members of the Executive Committee of Novartis. Mr. Hudson and Mr. Strigini report to Joseph Jimenez, CEO of Novartis.

In July 2016, we established the Global Drug Development (GDD) organization to oversee 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. Dr. Vas Narasimhan was appointed Global Head Drug Development and Chief Medical Officer, a newly created position in the ECN and reports to the CEO of Novartis. GDD includes approximately 10,000 associates worldwide.

In 2016, André Wyss, already a member of the ECN, Head Novartis Business Services (NBS) and Country President for Switzerland, was appointed President, Novartis Operations. In his new role, he assumed responsibility for the integrated Novartis Technical Operations (NTO) organization as well as for Global Public & Government Affairs, in addition to his previous responsibilities, and he continues to report to the CEO Novartis. NTO was established effective July 1, 2016, in order 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,

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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 28,000 associates and 67 manufacturing sites across our Innovative Medicines and Sandoz Divisions.

NBS, our shared service organization, was also made a part of Novartis Operations in 2016. NBS 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 10,000 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 2016, Novartis continuing operations achieved net sales of $48.5 billion, while net income from continuing operations amounted to $6.7 billion. Of total net sales from continuing operations, $11.9 billion, or 25%, came from Emerging Growth Markets, and $36.6 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 2016 amounted to $9.0 billion ($8.5 billion excluding impairment and amortization charges).

Headquartered in Basel, Switzerland, our Group companies employed 118,393 full-time equivalent associates as of December 31, 2016. Our products are sold in approximately 155 countries around the world.

**Innovative Medicines Division**

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

In 2016, the Innovative Medicines Division accounted for $32.6 billion, or 67%, of Group net sales, and for $7.4 billion, or 85%, 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 dermatology, respiratory, oncology, ophthalmics, cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies, 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 2016, Sandoz accounted for $10.1 billion, or 21%, of Group net sales, and for $1.4 billion, or 17%, 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

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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 2016, Alcon accounted for $5.8 billion, or 12%, of Group net sales, and for $ 0.1 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 therapeutic area of oncology. In August 2016, we decided to re-integrate activities conducted by Cell and Gene Therapies, previously a separate franchise in the Innovative Medicines Division (formerly named the Pharmaceuticals Division), into the Novartis Oncology business unit.

The Novartis Pharmaceuticals business unit is organized into global business franchises responsible for the commercialization of various products in the following therapeutic areas: Ophthalmology, Neuroscience, Immunology and Dermatology, 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 compliance with IFRS, Novartis updated its segment financial information to reflect these transfers, both for the current and prior years, to aid comparability of year-on-year results. As a result, all comparisons of divisional results from 2016, 2015 and 2014 in this Form 20-F reflect this new divisional structure.

The Innovative Medicines Division is the largest contributor among the divisions of Novartis and reported consolidated net sales of $32.6 billion in 2016, 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 intend to sell our marketed products throughout the world, not all products and indications are currently available in every country. Compounds and new indications in development are subject to required regulatory approvals and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. It may not be possible to obtain regulatory approval for any or all of the new compounds and new indications referred to in this Form 20-F in any country or in every country. See " Regulation" for further information on the approval process. Some of the products listed below have lost patent protection or are otherwise subject to generic competition. Others are subject to patent challenges by potential generic competitors. Please see " Intellectual Property" for general information on intellectual property and regulatory data protection, and for further information on the status of patents and exclusivity for Innovative Medicines Division products.

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***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 | Advanced renal cell carcinoma after failure of treatment with VEGF-targeted therapy | Tablet<br>Dispersible tablet for oral suspension |
| | | | Advanced neuroendocrine tumors of gastrointestinal, lung or pancreatic origin | |
| | | | Hormone receptor-positive advanced breast cancer in combination with an aromatase inhibitor, after prior endocrine therapy | |
| | | | Subependymal giant cell astrocytoma associated with tuberous sclerosis complex (TSC) in patients not requiring immediate surgery | |
| | | | Renal angiomyolipoma associated with TSC in patients not requiring immediate surgery | |
| | *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<br>Oral film-coated tablet |
| | *Farydak* | panobinostat | Relapsed and/or refractory multiple myeloma, in combination with bortezomib and dexamethasone, after at least two prior regimens including bortezomib and an immunomodulatory agent | Capsule |
| | *Femara* | letrozole | Hormone receptor-positive early breast cancer in postmenopausal women following surgery (upfront adjuvant | Tablet |

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| | | therapy) | |
| | | Early breast cancer in post-menopausal women following standard tamoxifen therapy (extended adjuvant therapy) | |
| | | Advanced breast cancer in post-menopausal women (both as first- and second-line therapies) | |
| *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 | |
| *Odomzo*[1] | sonidegib | Locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or is not a candidate for surgery or radiation therapy | Capsule |

(1) Subject to divestment pending closing of sale to Sun Pharma.

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| Business franchise | Product | Common name | Indications (vary by country and/or formulation) | Formulation |
|---|---|---|---|---|
| | *Proleukin* | aldesleukin | Metastatic renal cell carcinoma<br>Metastatic melanoma | Powder for injection or 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, immunoglobulins, or splenectomy | Tablet<br>Eltrombopag for oral suspension |
| | | | Thrombocytopenia in patients with chronic hepatitis C to allow initiation and maintenance of interferon-based therapy | |
| | | | Severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy | |
| | *Sandostatin LAR and Sandostatin* SC | octreotide acetate | Acromegaly | Vial<br>Ampoule/pre-filled syringe |
| | | | Symptom control for certain forms of neuroendocrine tumors | |
| | | | Delay of tumor progression in patients with midgut tumors | |
| | *Signifor and Signifor* LAR | pasireotide | Cushing's disease | Solution for subcutaneous injection in ampoule<br>Powder and solvent for suspension for IM injection |
| | | | Acromegaly | |
| | *Tafinlar* + *Mekinist* | dabrafenib + trametinib | Patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by a validated test | Capsule (*Tafinlar*) Tablet (*Mekinist*) |
| | *Tasigna* | nilotinib | Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec* | Capsule |
| | | | First-line chronic myeloid leukemia | |
| | *Tykerb* | lapatinib | In combination with capacitabine for the treatment of patients with HER2+ advanced or metastatic breast cancer who have progressed on prior trastuzumab therapy | Tablet |

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| | | 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 |

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**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 |
| | *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 | |
| | *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 | Eye drops |

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| | | | intraocular pressure reduction | |
| | *Systane* and *Systane Ultra* | polyethylene glycol 400 and propylene glycol | Temporary relief of burning and irritation due to dryness of the eye | Eye drops |
| | *Systane Balance* | propylene glycol | Temporary relief of burning and irritation due to dryness of the eye | Eye drops |
| | *Systane* Hydration | polyethylene glycol 400, propylene glycol and hyaluronic acid | Temporary relief of burning and irritation due to dryness of the eye | 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 |
| ***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 |
| ***Immunology and Dermatology*** | *Cosentyx* | secukinumab | Active ankylosing spondylitis | Lyophilized, pre-filled syringe; Auto-injector |
| | | | Active psoriatic arthritis | |
| | | | Moderate-to-severe plaque psoriasis | |
| | | | Pustular psoriasis | |
| | *Ilaris* | canakinumab | Cryopyrin-associated periodic syndromes | Lyophilized powder for reconstitution for subcutaneous injection |
| | | | Tumor necrosis factor-receptor associated periodic syndrome | Solution for injection |
| | | | 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 |

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| Business franchise | Product | Common name | Indications (vary by country and/or formulation) | Formulation |
|---|---|---|---|---|
| | *Neoral/Sandimmune* | cyclosporine, USP Modified | Prevention of rejection following certain organ transplantation | Capsule<br>Oral solution<br>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 | Lyophilized powder in vial and liquid formulation in pre-filled syringe |
| | | | See also, "Respiratory" | |
| | *Zortress/ Certican* | everolimus | Prevention of organ rejection (heart, liver and kidney) | Tablet<br>Dispersible tablet |
| ***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 | Severe allergic asthma | Lyophilized powder in vial and liquid formulation in pre-filled syringe |
| | | | See also, "Immunology and Dermatology" | |
| ***Cardio-Metabolic*** | *Entresto* | sacubitril and valsartan | Symptomatic chronic heart failure with reduced ejection fraction | Tablet |
| | *Eucreas* | vildagliptin and metformin | Type 2 diabetes | Tablet |
| | *Galvus* | vildagliptin | Type 2 diabetes | Tablet |
| ***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) | Tablet |

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| | | fluctuations | |
| *Diovan* | valsartan | Hypertension | Tablet<br>Capsule<br>Oral solution |
| | | Heart failure | |
| | | Post-myocardial infarction | |
| *Diovan HCT/Co-Diovan* | valsartan and hydrochlorothiazide | Hypertension | Tablet |
| *Exelon* | rivastigmine | Mild-to-moderate Alzheimer's disease dementia | Capsule<br>Oral solution<br>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<br>Capsule |
| *Lamisil* | terbinafine (terbinafine hydrochloride) | Fungal infection of the skin and nails caused by dermatophyte fungi tinea capitis | Tablet |
| | | Fungal infections of the skin for the treatment of tinea corporis, tinea cruris, tinea pedis and yeast infections of the skin caused by the genus candida | |
| | | Onychomycosis of the toenail or fingernail due to dermatophytes | |

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| Business franchise | Product | Common name | Indications (vary by country and/or formulation) | Formulation |
|---|---|---|---|---|
| | *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 | Tablet<br>Chewable tablet<br>Oral suspension<br>Suppository |
| | | | 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 | |
| | *TOBI and TOBI Podhaler* | tobramycin | Pseudomonas aeruginosa infection in cystic fibrosis | Nebulizer solution (*TOBI)*<br>Inhalation powder (*TOBI Podhaler*) |
| | *Trileptal* | oxcarbazepine | Epilepsy | Tablet<br>Oral suspension |
| | *Tyzeka/Sebivo* | telbivudine | Chronic hepatitis B | Tablet<br>Oral solution |
| | *Voltaren/Cataflam* | diclofenac sodium/potassium/resinate/free acid | Inflammatory and degenerative forms of rheumatism | Tablet<br>Capsule |
| | | | Post traumatic and post-operative pain, inflammation and swelling | Oral drops/oral suspension<br>Ampoule for injection<br>Suppository |

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|---|---|
| Painful and/or inflammatory conditions in gynecology | Gel<br>Powder for oral solution<br>Transdermal patch |
| Other painful and/or inflammatory conditions such as renal and biliary colic, migraine attacks and as adjuvant in severe ear, nose and throat infections | |

***Key Marketed Products***

**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 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 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.

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*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.

*Sandostatin* SC and *Sandostatin LAR* (octreotide acetate/octreotide acetate for injectable suspension) are somatostatin analogues indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of pituitary growth hormone in adults. *Sandostatin* is also indicated for the treatment of patients with certain symptoms associated with carcinoid tumors and other types of gastrointestinal and pancreatic neuroendocrine tumors. Additionally, *Sandostatin LAR* is approved in more than 60 countries for treatment of patients with advanced neuroendocrine tumors of the midgut or unknown primary tumor location. *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 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 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 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.

*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 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 formulation. Regulatory applications for the granules formulation have been submitted under the name *Jadenu* in the US and Japan and under the name *Exjade* in the EU.

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

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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 advanced STS. *Votrient* was acquired from GSK.

*Tafinlar* + *Mekinist* (dabrafenib + trametinib) is the first combination of its kind for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma, as detected by a validated test, in the US, EU and several other markets. *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 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.

*Jakavi* (ruxolitinib) is an oral inhibitor of the JAK1 and JAK2 tyrosine kinases. It is the first JAK inhibitor indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis and adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. *Jakavi* is currently approved in more than 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 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.

**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 licensed for six ocular indications: neovascular age-related macular degeneration (nAMD), visual impairment due to diabetic macular edema (DME), visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO), visual

impairment due to macular edema

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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) secondary to other pathologies. Approval in visual impairment due to CNV secondary to other pathologies was received in Europe in November 2016, and submissions for this indication have been filed in 22 other countries. In April 2016 the label of *Lucentis* was updated to include the treatment of RVO patients with retinal ischemia. *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, 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. For further information see "Note 27. Transactions with related parties  Genentech/Roche" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

*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 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.

*Systane* (polyethylene glycol 400 and propylene glycol) and most other *Systane* branded products are indicated for the temporary relief of burning and irritation due to dryness of the eye. The *Systane* portfolio includes products for daily and nighttime relief, as well as products for everyday lid hygiene, and for discomfort associated with contact lens wear. *Systane Ultra* (polyethylene glycol 400 and propylene glycol) is sold in more than 80 countries, including the US, Canada and countries of the EU, Latin America and Asia. *Systane Balance* (propylene glycol) is sold in more than 60 countries. *Systane* Hydration (polyethylene glycol 400, propylene glycol and hyaluronic acid) was launched in March 2015 and is now sold in more than 35 countries across Europe, plus Canada and Australia.

*Patanol* (olopatadine), *Pataday* (olopatadine) and *Pazeo* (olopatadine) are olopatadine hydrochloride ophthalmic solutions of different concentrations that are approved to treat the signs and symptoms of allergic conjunctivitis (*Patanol*), as well as ocular itching associated with allergic conjunctivitis (*Pataday* and *Pazeo*). Olopatadine products are marketed in more than 100 countries, including the US, countries of the EU, Canada and China.

*Neuroscience*

*Gilenya* (fingolimod) is the first oral therapy approved to treat relapsing forms of multiple sclerosis (RMS) and the first in a new class of compounds called sphingosine 1-phosphate receptor modulators. In the US, *Gilenya* is indicated for relapsing forms of MS. In the EU, *Gilenya* is indicated for adult patients with high disease activity despite treatment with at least one disease modifying agent, or rapidly evolving severe relapsing-remitting MS. *Gilenya* 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.

*Immunology and Dermatology*

*Cosentyx* (secukinumab) 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

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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).

*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.

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

*Myfortic* (enteric-coated formulation of mycophenolate sodium) is approved in more than 90 countries for the prevention of acute rejection of kidney allografts, and is indicated in combination with cyclosporine and corticosteroids. *Myfortic* was first approved in the US in 2004 and in the EU in 2003.

*Ilaris* (canakinumab) is a human monoclonal antibody that selectively binds and neutralizes interleukin-1β (IL-1β), a pro-inflammatory cytokine. Since 2009, *Ilaris* has been approved in more than 70 countries for the treatment of children and adults suffering from cryopyrin-associated periodic syndromes, a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life-threatening amyloidosis. In 2013, *Ilaris* was approved in the EU for the treatment of acute gouty arthritis in patients who cannot be managed with standard of care, and in the US, EU and other countries for the treatment of systemic juvenile idiopathic arthritis. In 2016, the FDA granted three simultaneous approvals for the expanded use of *Ilaris* to treat three rare and distinct types of periodic fever syndromes: tumor necrosis factor-receptor associated periodic syndrome, hyperimmunoglobulin D syndrome / mevalonate kinase deficiency and familial Mediterranean fever. *Ilaris* is the first and only FDA approved biologic treatment for these rare autoinflammatory diseases, which are also referred to as Hereditary Periodic Fevers. In December 2016, the CHMP recommended approval of the same three Periodic Fever Syndromes. In 2016, the European Commission also approved a license extension for *Ilaris* to treat patients with Adult-Onset Still's Disease.

*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)/chronic idiopathic urticaria (CIU) including approvals in the EU as add-on therapy for the treatment of CSU in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment, and, in the US, for the treatment of adults and adolescents (12 years of age and above) with CIU who remain symptomatic despite H1 antihistamine treatment. See also, *Xolair* in "Respiratory" below. We co-promote *Xolair* with Genentech in the US and share a portion of operating income, but we do not record any US sales. Novartis records all sales of *Xolair* outside the US. For further information see "Note 27. Transactions with related parties  Genentech/Roche" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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*Respiratory*

*Xolair* (omalizumab) 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. 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 27. Transactions with related parties  Genentech/Roche" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

*Ultibro Breezhaler* (indacaterol/glycopyrronium bromide) / *Utibron Neohaler* (indacaterol/ glycopyrrolate) is a fixed-dose combination of the long-acting beta$_2$-adrenergic agonist (LABA) indacaterol and the long-acting muscarinic antagonist (LAMA) glycopyrronium bromide. *Ultibro Breezhaler* was approved in the EU in 2013 as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD), and in Japan the MHLW approved *Ultibro* Inhalation Capsules delivered through the low resistance *Breezhaler* inhalation device, for relief of various symptoms due to airway obstruction in COPD (chronic bronchitis, emphysema). In October 2015 the combination was approved in the US under the name *Utibron Neohaler* as a twice-daily dual bronchodilator for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. The combination is approved in more than 90 countries and launched in more than 50 countries. The LAMA glycopyrronium bromide is approved individually as once-daily *Seebri Breezhaler* in the EU, *Seebri* (glycopyrronium) Inhalation Capsules 50 mcg administered through the *Breezhaler* device in Japan, and twice-daily *Seebri Neohaler* in the US, where the active ingredient is known as glycopyrrolate. It is now approved in more than 90 countries worldwide. Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura. The LABA indacaterol is approved individually as once-daily *Onbrez Breezhaler* in the EU, *Onbrez* Inhalation Capsules delivered through the *Breezhaler* inhalation device in Japan, and *Arcapta Neohaler* in the US. It is now approved in more than 100 countries worldwide. In December 2016, Sunovion Pharmaceuticals Inc., acquired the US commercialization rights for *Utibron Neohaler, Arcapta Neohaler* and *Seebri Neohaler.* Novartis will continue to market *Ultibro Breezhaler, Onbrez Breezhaler* and *Seebri Breezhaler* outside of the US.

*Cardio-Metabolic*

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

*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 and launched in the US in July 2015 as a treatment for HFrEF. It was approved in Switzerland in September 2015 and in the EU in November 2015. *Entresto* is now approved

in more than 70 countries, and launched in more than 30 countries, for the treatment of HFrEF, including the US, countries of the EU, Switzerland, Canada and Australia. Both ESC HF and US HF guidelines have given a class I recommendation, the strongest class of recommendation, for the use of sacubitril/valsartan in patients with HFrEF.

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*Established Medicines*

*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 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.

*Exforge* (valsartan and amlodipine besylate) is a single-pill combination of the ARB *Diovan* and the calcium channel blocker amlodipine besylate. First approved for the treatment of high blood pressure in Switzerland in 2006, and in the US and EU in 2007, it is now available in more than 100 countries. *Exforge HCT* (valsartan, amlodipine besylate and hydrochlorothiazide) is a single pill combining three widely prescribed high blood pressure treatments: an ARB, a calcium channel blocker and a diuretic (hydrochlorothiazide). *Exforge HCT* was approved in the EU and the US in 2009, and is now available in more than 75 countries.

*Voltaren/Cataflam* (diclofenac sodium/potassium/resinate/free acid) is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions. *Voltaren/Cataflam* was first registered in 1973 and is available in more than 140 countries. This product 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.

*Exelon* (rivastigmine tartrate) and *Exelon* Patch (rivastigmine transdermal system) are cholinesterase inhibitors indicated for the treatment of Alzheimer's disease (AD) dementia and Parkinson's disease (PD) dementia. They are the oral and transdermal formulations, respectively, of the cholinesterase inhibitor rivastigmine. *Exelon* capsules have been available since 1997 to treat mild to moderate AD dementia and are approved in more than 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.

*Ritalin, Ritalin LA, Focalin* and *Focalin XR* (methylphenidate HCl, methylphenidate HCl extended release, dexmethylphenidate HCl and dexmethylphenidate HCl extended release) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children. *Ritalin LA* and *Focalin XR* are additionally indicated for ADHD in adults. *Ritalin* is also indicated for narcolepsy. *Ritalin* was first marketed during the 1950s and is available in more than 70 countries. *Ritalin LA* is available in more than 30 countries. *Focalin* comprises the active d-isomer of methylphenidate and therefore requires half the dose of *Ritalin*. *Focalin* and *Focalin XR* are available in the US.

**Compounds in Development**

The following table and paragraph summaries provide an overview of the key projects currently in the Confirmatory Development stage within our Innovative Medicines Division, including projects seeking to develop potential uses of new molecular entities as well as potential additional indications or new formulations for already marketed products. The year that each project entered the current phase of development disclosed below reflects

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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 | 2015 | 2020/I |
| ACZ885 | canakinumab | Anti-interleukin-1β monoclonal antibody | Secondary prevention of cardiovascular events | Cardio-Metabolic | Subcutaneous injection | 2011 | 2017/III |
| *Afinitor/Votubia* | everolimus | mTOR inhibitor | Tuberous sclerosis complex seizures | Oncology | Oral | EU: 2016<br>US: 2013 | EU (registration)<br>US 2017/III |
| AMG 334 | erenumab | Selective CGRP receptor antagonist | Migraine | Neuroscience | Subcutaneous injection | 2015 | 2017/III |
| *Arzerra* | ofatumumab | Anti-CD20 monoclonal antibody | Refractory non-Hodgkin's lymphoma | Oncology | Oral | 2010 | 2018/III |
| BAF312 | siponimod | Sphingosine-1-phosphate receptor modulator | Secondary progressive multiple sclerosis | Neuroscience | Oral | 2012 | 2019/III[(1)] |
| BYL719 | alpelisib | PI3Kα inhibitor | Hormone receptor-positive, HER2-negative advanced breast cancer (postmenopausal women), 2nd line (+ fulvestrant) | Oncology | Oral | 2015 | 2019/III |
| BYM338 | bimagrumab | Inhibitor of activin receptor Type II | Hip fracture | Neuroscience | Intravenous infusion | 2013 | ≥2021/II |
| | | | Sarcopenia | Neuroscience | Intravenous infusion | 2014 | ≥2021/II |
| CAD106 | amilomotide | Beta-amyloid-protein therapy | Alzheimer's disease | Neuroscience | Intramuscular injection | 2008 | ≥2021/ II/III |
| CJM112 | TBD | Anti-interleukin-17 monoclonal antibody | Immune disorders | Immunology and Dermatology | Subcutaneous injection | 2015 | ≥2021/II |
| CNP520 | TBD | BACE inhibitor | Alzheimer's disease | Neuroscience | Oral | 2015 | ≥2021/ I/II |
| *Cosentyx* | secukinumab | Anti-interleukin-17 monoclonal antibody | Non-radiographic axial | Immunology and Dermatology | Subcutaneous injection | 2015 | 2018/III |

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|---|---|---|---|---|---|---|---|
| | | | spondyloarthritis | | | | |
| | | | Psoriatic arthritis head-to-head study vs. adalimumab | Immunology and Dermatology | Subcutaneous injection | 2016 | 2020/III |
| | | | Ankylosing spondylitis head-to-head study vs. adalimumab | Immunology and Dermatology | Subcutaneous injection | 2016 | ≥2021/III |
| CTL019 | tisagenlecleucel-T | CD19-targeted chimeric antigen receptor T-cell immunotherapy | Pediatric acute lymphoblastic leukemia | Oncology | Intravenous infusion | 2012 | 2017/II |
| | | | Diffuse large B-cell lymphoma | Oncology | Intravenous infusion | 2014 | 2017/II |

(1) Ongoing discussions with health authorities to agree on next steps.

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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 |
|---|---|---|---|---|---|---|---|
| EMA401 | TBD | Angiotensin II receptor antagonist | Neuropathic pain | Neuroscience | Oral | 2011 | ≥2021/II |
| *Entresto* | valsartan and sacubitril (as sodium salt complex) | Angiotensin receptor/ neprilysin inhibitor | Chronic heart failure with preserved ejection fraction | Cardio-Metabolic | Oral | 2013 | 2019/III |
| | | | Post-acute myocardial infarction | Cardio-Metabolic | Oral | 2015 | 2020/III |
| FTY720 | fingolimod | Sphingosine-1-phosphate receptor modulator | Pediatric multiple sclerosis | Neuroscience | Oral | 2013 | 2017/III |
| *Ilaris* | canakinumab | Anti-interleukin-1β monoclonal antibody | Periodic fever syndromes | Immunology and Dermatology | Subcutaneous injection | 2016 | US (approved) EU (registration) |
| INC280 | capmatinib | c-MET inhibitor | Non-small cell lung cancer | Oncology | Oral | 2013 | 2018/II |
| | | | Non-small cell lung cancer EGFR mutation | Oncology | Oral | 2016 | ≥2021/II |
| *Jakavi* | ruxolitinib | JAK1/JAK2 inhibitor | Early myelofibrosis | Oncology | Oral | 2016 | 2020/III |
| | | | Graft-versus-host disease | Oncology | Oral | 2016 | 2019/III |
| KAE609 | cipargamin | PfATP4 inhibitor | Malaria | Established Medicines | Oral | 2012 | ≥2021/II |
| KAF156 | TBD | Imidazolopiperazines derivative | Malaria | Established Medicines | Oral | 2013 | ≥2021/II |
| LAM320 | clofazimine | Mycobacterial DNA binding | Multi-drug resistant tuberculosis | Established Medicines | Oral | 2016 | 2018/III |
| LCI699 | osilodrostat | Aldosterone synthase inhibitor | Cushing's disease | Oncology | Oral | 2011 | 2018/III |
| LEE011 | ribociclib | CDK4/6 inhibitor | Hormone receptor-positive, HER2-negative advanced breast cancer (postmenopausal women), 1st line (+ letrozole) | Oncology | Oral | 2016 | US/EU (registration) |
| | | | Hormone receptor-positive, | Oncology | Oral | 2015 | 2018/III |

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|---|---|---|---|---|---|---|---|
| | | | HER2-negative advanced breast cancer (postmenopausal women), 1st/2nd line (+ fulvestrant) | | | | |
| | | | Hormone receptor-positive, HER2-negative advanced breast cancer (premenopausal women), 1st line, (+ tamoxifen + goserelin or NSAI + goserelin) | Oncology | Oral | 2014 | 2018/III |
| | | | Hormone receptor-positive, HER2-negative breast cancer (adjuvant) | Oncology | Oral | 2016 | ≥2021/III |
| LIK066 | TBD | SGLT 1/2 inhibitor | Weight loss | Cardio-Metabolic | Oral | 2016 | ≥2021/II |
| LJN452 | TBD | FXR agonist | Non-alcoholic steatohepatitis | Immunology and Dermatology | Oral | 2015 | ≥2021/II |
| *Lucentis* | ranibizumab | Anti-VEGF monoclonal antibody fragment | Retinopathy of prematurity | Ophthalmology | Intravitreal injection | 2014 | 2018/III |
| OMB157 | ofatumumab | Anti-CD20 monoclonal antibody | Relapsing multiple sclerosis | Neuroscience | Subcutaneous injection | 2016 | 2019/III |
| PIM447 | TBD | Pan-PIM inhibitor | Hematologic tumors | Oncology | Oral | 2015 | ≥2021/I |
| PKC412 | midostaurin | Signal transduction inhibitor | Acute myeloid leukemia | Oncology | Oral | 2016 | US/EU (registration) |
| | | | Advanced systemic mastocytosis | Oncology | Oral | 2016 | US/EU (registration) |
| | | | Acute myeloid leukemia (FLT3 wild type) | Oncology | Oral | 2016 | ≥2021/III |
| *Promacta/Revolade* | eltrombopag | Thrombopoietin receptor agonist | Severe aplastic anemia, 1st line | Oncology | Oral | 2016 | 2017/III |

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| Project/Product | Common name | Mechanism of action | Potential indication/ Disease area | Business franchise | Formulation/ Route of administration | Year Project Entered Current Development Phase | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|---|
| QAW039 | fevipiprant | CRTH2 antagonist | Asthma | Respiratory | Oral | 2010 | 2019/III |
| | | | Atopic dermatitis | Immunology and Dermatology | Oral | 2013 | ≥2021/II |
| QBW251 | TBD | CFTR potentiator | Cystic fibrosis | Respiratory | Oral | 2016 | ≥2021/II |
| QGE031 | ligelizumab | High affinity anti-IgE monoclonal antibody | Chronic spontaneous urticaria/ chronic idiopathic urticaria | Immunology and Dermatology | Subcutaneous injection | 2015 | 2020/II |
| QMF149 | indacaterol, mometasone furoate (in fixed dose combination) | Long-acting beta2-adrenergic agonist and inhaled corticosteroid | Asthma | Respiratory | Inhalation | 2015 | 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 |
| RLX030 | serelaxin | Recombinant form of human relaxin-2 hormone | Acute heart failure | Cardio-Metabolic | Intravenous infusion | 2009 | 2017/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 | 2016 | 2020/III |
| SEG101 | crizanlizumab | P-selectin inhibitor | Sickle cell disease | Oncology | Intravenous infusion | 2016 | 2020/III |
| *Signifor LAR* | pasireotide | Somatostatin analogue | Cushing's disease | Oncology | Long-acting release/ intramuscular injection | 2016 | US[(2)] /EU (registration) |
| *Tafinlar* + *Mekinist* | dabrafenib + trametinib | BRAF inhibitor + MEK inhibitor | BRAF V600+ non-small cell lung cancer | Oncology | Oral | 2016 | US/EU (registration) |
| | | | BRAF V600+ melanoma (adjuvant) | Oncology | Oral | 2013 | 2018/III |

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|---|---|---|---|---|---|---|---|
| | | | BRAF V600+ colorectal cancer | Oncology | Oral | 2012 | 2020/ I/II |
| *Tasigna* | nilotinib | BCR-ABL inhibitor | Chronic myeloid leukemia treatment-free remission | Oncology | Oral | EU: 2016 US: 2012 | EU (registration) US 2017/III |
| UNR844 | TBD | Reduction of disulfide bonds | Presbyopia | Ophthalmology | Eye drops | 2016 | ≥2021/II |
| VAY736 | TBD | Anti-BAFF (B-cell activating factor) monoclonal antibody | Primary Sjoegren's syndrome | Immunology and Dermatology | Subcutaneous injection | 2015 | ≥2021/II |
| ZPL389 | TBD | Histamine $H_4$ receptor antagonist | Atopic dermatitis | Immunology and Dermatology | Oral | 2016 | ≥2021/II |
| *Zykadia* | ceritinib | ALK inhibitor | ALK+ advanced non-small cell lung cancer (1st line, treatment naïve) | Oncology | Oral | 2016 | US/EU (registration) |
| | | | ALK+ advanced non-small cell lung cancer (brain metastases) | Oncology | Oral | 2015 | 2019/II |

(2) Submission pending acceptance by FDA.

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***Key Development Projects***

ACZ885 (canakinumab) was first approved in 2009 for cryopyrin-associated periodic syndromes as *Ilaris*. ACZ885 is currently being investigated in the fully enrolled pivotal Phase III CANTOS study to determine whether ACZ885 can reduce the risk of recurrent cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke) in patients with history of myocardial infarction and elevated inflammatory burden versus placebo when administered quarterly in addition to standard of care. Results from the CANTOS study are expected mid-2017.

*Afinitor/Votubia* and *Afinitor Disperz* (everolimus) are oral inhibitors of the mTOR pathway. The EXIST-3 Phase III clinical trial in patients with tuberous sclerosis complex (TSC) who have refractory partial-onset seizures (uncontrollable seizures localized to a specific area of the brain) found that adjunctive therapy with everolimus significantly reduced refractory seizures associated with TSC compared to placebo in patients receiving a stable regimen of 1 - 3 anti-epileptic drugs. This data was published in The Lancet in September 2016. In December 2016, *Votubia* was recommended by the CHMP for approval as an adjunctive treatment of patients aged two years and older whose refractory partial-onset seizures, with or without secondary generalization, are associated with TSC.

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. In 2016, we announced positive results for a Phase II study of AMG 334 in chronic migraine prevention and for two Phase III studies of AMG 334 in episodic migraine prevention. In these studies, patients who received AMG 334 experienced fewer monthly migraine days than patients who received placebo. The safety profile of AMG 334 was comparable to placebo in the trials. AMG 334 is being co-developed by Novartis and Amgen. Novartis has commercial rights to AMG 334 outside of the US, Canada and Japan.

*Arzerra* (ofatumumab) is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of chronic lymphocytic leukemia (CLL) cells and normal B lymphocytes. Results from the Phase III PROLONG study evaluating ofatumumab maintenance therapy versus no further treatment (observation) in patients with relapsed CLL who responded to induction treatment at relapse formed the basis for submissions made in 2015 to the EMA and FDA for this indication. In September 2015, the FDA granted Priority Review for ofatumumab as maintenance therapy in relapsed CLL, and in January 2016 the FDA approved *Arzerra* for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. In the EU, the CHMP did not recommend approval for *Arzerra* as maintenance treatment for patients with relapsed CLL. Results from the Phase III COMPLEMENT 2 study in 2015 showed that treatment with ofatumumab plus fludarabine and cyclophosphamide significantly improved median progression-free survival by 54% compared to treatment with fludarabine and cyclophosphamide alone in patients with relapsed CLL. Results of this study were submitted to the EMA and FDA in 2016. In May 2016, the FDA granted Priority Review for ofatumumab in combination with fludarabine and cyclophosphamide in relapsed CLL and approved this indication in August 2016. In November 2016, the CHMP issued a positive opinion for ofatumumab in combination with fludarabine and cyclophosphamide in relapsed CLL, which was followed in December 2016 by European Commission approval of the product for use in this indication. A Phase III trial is also underway to investigate ofatumumab in refractory non-Hodgkin's lymphoma. *Arzerra* is marketed under a license agreement between Genmab A/S and Novartis. Novartis is also investigating ofatumumab (disclosed as OMB157) in two Phase III studies for relapsing multiple sclerosis.

BAF312 (siponimod) is an oral, second-generation sphingosine 1-phosphate receptor modulator in Phase III development for secondary progressive multiple sclerosis. BAF312 binds selectively to the sphingosine 1-phosphate receptor subtypes 1 and 5, and distributes effectively to the brain where it may modulate central S1P1,5 receptors to impact central nervous system inflammation and repair mechanisms. Results from the EXPAND Phase III study, evaluating the efficacy and safety of BAF312 for secondary progressive multiple sclerosis, were announced in August 2016. EXPAND met its primary endpoint and showed that treatment with BAF312 reduced the risk of three-month confirmed disability progression by 21% and six-month confirmed disability progression by 26% compared with placebo. A consistent reduction in the risk of confirmed disability progression was seen across predefined subgroups, including patients without relapses. BAF312 was generally safe and well tolerated, with a profile comparable to

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other drugs in the same class. Novartis is currently in discussions with health authorities about next steps with BAF312.

BYL719 (alpelisib) is an orally bioavailable, alpha isoform-specific PI3K inhibitor. In breast cancer cell lines harboring PIK3CA mutations, BYL719 has been shown to inhibit the PI3K/AKT/mTOR pathway and have anti-proliferative effects. In addition, cancer cell lines with PIK3CA mutations were more sensitive to alpelisib than those without the mutation across a broad range of different cancers. BYL719 is 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 circulating IL-17A. In January 2016, *Cosentyx* was approved by the FDA for the treatment of adults with ankylosing spondylitis (AS) and for the treatment of adults with psoriatic arthritis (PsA). In October 2016, the Swiss health authority Swissmedic also approved *Cosentyx* for the treatment of AS and PsA. New results for *Cosentyx* published in the Journal of the American Academy of Dermatology from the head-to-head CLEAR study showed that *Cosentyx* remains superior to Stelara® in sustaining skin clearance (PASI 90 to PASI 100) at 52 weeks for adults with moderate-to-severe psoriasis. In addition, long-term data from the Phase III SCULPTURE study presented at a European medical meeting in October 2016 showed that *Cosentyx* delivers high and long-lasting skin clearance in patients with moderate-to-severe plaque psoriasis out to four years of treatment. Secukinumab is also in Phase III development for non-radiographic axial spondyloarthritis, and new head-to-head clinical trials have been initiated in AS and PsA to compare *Cosentyx* versus adalimumab.

CTL019 (tisagenlecleucel-T) is an investigational therapy that utilizes chimeric antigen receptors (CARs) to use the patient's own immune system to fight certain types of cancer. CARs are engineered proteins that transform a patient's own T cells into antigen-specific cells which seek out target proteins present on a patient's cancerous tumor. When these cells are re-introduced into the patient's blood, they demonstrate the potential to bind to the cancer cells and destroy them. CTL019 targets a protein called CD19 that is associated with a number of B-cell malignancies. Data presented in December 2016 from the pivotal global Phase II ELIANA trial of CTL019 in relapsed/refractory pediatric and young adult patients with B-cell acute lymphoblastic leukemia showed that 82% of infused patients achieved complete remission or complete remission with incomplete blood count recovery at three months post CTL019 infusion. For all patients with complete remission, no minimal residual disease was detected. In addition, the estimated relapse-free rate among responders was 60% six months after infusion with CTL019. We plan to submit a BLA to the FDA on the basis of this data in early 2017. CTL019 is also being studied in a Phase II trial in diffuse large B-cell lymphoma with an FDA filing planned in 2017.

EMA401 is a novel angiotensin II Type 2 receptor ($AT_2R$) antagonist in Phase II development. Targeting $AT_2R$ is an emerging approach to neuropathic pain treatment. $AT_2R$ antagonists block the pain signaling pathways in the peripheral nervous system. Positive results from a Phase II clinical trial of EMA401 in post-herpetic neuralgia, a painful condition that develops in some people following herpes zoster (shingles), were published in a major medical journal in February 2014. In addition, thus far, EMA401 has not been associated with central nervous system side effects such as dizziness or confusion, which are typically associated with existing therapies. Novartis expects to start two Phase II studies to assess the potential of EMA401 in peripheral neuropathic pain in 2017.

*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 (HFrEF). 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 has commenced 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.

FTY720 (fingolimod) is a sphingosine 1-phosphate receptor modulator approved for the treatment of relapsing forms of multiple sclerosis as *Gilenya*. A Phase III study of fingolimod in pediatric multiple sclerosis was initiated in 2013. Results from the study are anticipated in 2017.

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*Jakavi* (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. The Phase III study ReTHINK was initiated in the first quarter of 2016 to evaluate the efficacy and safety of *Jakavi* in early myelofibrosis patients. 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.

LEE011 (ribociclib) is a selective cyclin dependent kinase inhibitor that inhibits two proteins called cyclin dependent kinase 4 and 6 (CDK4/6). Results from the pivotal Phase III MONALEESA-2 study showed LEE011 plus letrozole significantly extended progression-free survival (PFS) compared to a standard of care, letrozole, as a first-line treatment in post-menopausal women with HR+/HER2 advanced breast cancer. LEE011 plus letrozole reduced the risk of disease progression or death by 44% over letrozole alone, significantly extending PFS across all patient subgroups. Results from additional analyses from the Phase III MONALEESA-2 study showed that LEE011 plus letrozole significantly prolonged PFS across various pre-planned patient subgroups with HR+/HER2 advanced or metastatic breast cancer, including post-menopausal women diagnosed de novo, those with visceral metastases (liver and/or lung involvement), and those with bone-only disease. These findings demonstrate the potential impact of LEE011 plus letrozole in the first-line setting, showing that treatment benefit was evident across relevant patient subgroups regardless of their disease burden or tumor location, including those patients with more aggressive disease. We presented this data at the San Antonio Breast Cancer Symposium in December 2016. In November 2016, Novartis announced that the FDA granted Priority Review for LEE011 as first-line treatment of postmenopausal women with HR+/HER2 advanced or metastatic breast cancer in combination with letrozole following a Breakthrough Therapy designation from the FDA in August 2016. Novartis also announced in November that the EMA has accepted for review the marketing authorization application for LEE011 plus letrozole in the same patient population. Novartis is continuing to assess LEE011 through the MONALEESA clinical trial program, which includes MONALEESA-2, MONALEESA-3 and MONALEESA-7. These trials are evaluating LEE011 in multiple endocrine therapy combinations across a broad range of patients, including men and premenopausal women. LEE011 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 bio markers. We expect to initiate Phase II dose ranging studies for weight loss in the first half of 2017.

LJN452 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. We expect to complete the Phase III program in MS in 2019. Ofatumumab is marketed by Novartis for oncology indications as intravenous infusion under the brand name *Arzerra*.

Pegpleranib is an oligo-nucleotide aptamer that inhibits the action of platelet-derived growth factor (PDGF). The pegpleranib Phase III program originally consisted of three clinical trials to evaluate the safety and efficacy of pegpleranib in combination with anti-VEGF drugs for the treatment of neovascular age related macular degeneration (nAMD). In December 2016, Novartis announced initial topline results from two pivotal Phase III clinical studies evaluating the safety and efficacy of pegpleranib in combination with *Lucentis* (ranibizumab) for the treatment of nAMD. These studies, OPH1002 and OPH1003, sponsored by Ophthotech Corporation, did not meet the primary endpoint of superiority for the

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pegpleranib and ranibizumab combination therapy, measured as best corrected visual acuity in terms of additional letter gains over ranibizumab monotherapy. In November 2015, Genentech entered into an agreement with Novartis to participate in certain financial rights related to the Novartis licensing and commercialization agreement with Ophthotech Corporation for pegpleranib. We continue to hold the license for the rights to develop and exclusively market pegpleranib outside the US.

PKC412 (midostaurin) is an oral, multi-targeted kinase inhibitor in Phase III development for treatment of patients with FLT3-mutated acute myeloid leukemia (AML) and for advanced systemic mastocytosis (SM). In February 2016, the FDA granted PKC412 Breakthrough Therapy designation for FLT3-mutated AML, which was primarily based upon the positive results from the Phase III randomized versus placebo RATIFY clinical trial and in November 2016, the FDA granted Priority Review to the PKC412 new drug application for the treatment of newly diagnosed FLT3 mutation-positive AML and advanced SM. In the RATIFY study, patients who received PKC412 plus standard induction and consolidation chemotherapy and as monotherapy up to one year for maintenance experienced a 23% improvement in overall survival compared to those treated with standard induction/consolidation chemotherapy and placebo. The median overall survival for patients in the PKC412 treatment group was 74.7 months, versus 26.0 months for patients in the placebo group. PKC412 is the first compound to illustrate an overall survival benefit targeting FLT3 in AML. In an advanced SM pivotal Phase II study, PKC412 demonstrated an overall response rate, defined as a major or partial response, of 60% in patients. The median duration of response for all responders in the primary efficacy population was 24.1 months. These data are the basis for the worldwide regulatory filings for PKC412 for newly diagnosed, FLT3-mutated AML and for advanced SM, including the FDA and EMA.

QAW039 (fevipiprant) is a small molecule being investigated in the reduction of frequency and duration of asthma attacks, particularly in patients with severe asthma. This compound is designed to block the activity of T-helper type-2 (Th2) cells, which are thought to contribute to the disease by releasing signals that maintain eosinophilic airway inflammation. In a Phase II study completed in August 2015, QAW039 reduced eosinophils, drivers of airway inflammation in patients with persistent moderate-to-severe asthma. Pivotal Phase III trials are underway in severe asthma.

QVM149 (indacaterol, glycopyrronium, mometasone furoate) is a once daily fixed-dose triple combination therapy being investigated in moderate-to-severe asthma patients who are uncontrolled on a long-acting beta-agonist (LABA) combined with an inhaled corticosteroid (ICS) or who are already taking a triple combination LABA, long-acting muscarinic antagonist (LAMA) and ICS. QVM149 consists of indacaterol (a LABA), glycopyrronium (a LAMA) and mometasone furoate (an ICS) delivered via the *Breezhaler* device. QVM149 is currently in Phase III clinical trials. This Phase III program is also designed to deliver data to support regulatory filings by Novartis for QMF149, a once daily combination of indacaterol and mometasone fuorate. This Phase III program is to support registration of QVM149 and QMF149 outside the US only.

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. Results from the Phase III RELAX-AHF study showed that RLX030 improved symptoms and reduced mortality in patients with acute heart failure (AHF). Data were presented at the American Heart Association congress in 2012 and published simultaneously in The Lancet. In 2014, the FDA and CHMP decided that further data were required for marketing authorizations to be granted and a second confirmatory Phase III study, RELAX-AHF-2, is currently underway. The study's primary endpoint is a reduction in cardiovascular mortality, and top line results are expected in the first half of 2017. Based on the first study RELAX-AHF, RLX030 was approved and launched in Russia in 2014 under the trade name *Reasanz*.

RTH258 (brolucizumab) is a novel anti-vascular endothelial growth factor (anti-VEGF) agent that is currently being tested in neovascular age-related macular degeneration (nAMD) patients. RTH258 is a single chain antibody fragment that may be longer-acting than currently approved treatments for AMD, potentially enabling patients to extend the time between treatments. We expect the results of two Phase III trials in 2017.

SEG101 (crizanlizumab, formerly SelG1) 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

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2016 by exercising its right to acquire Selexys Pharmaceuticals Corporation following receipt of results of the Phase II SUSTAIN study. Results from the SUSTAIN study showed 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 in development as a long-acting release formulation for patients with Cushing's disease. Applications have been submitted to the FDA and EMA for this indication.

*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* is the first combination of BRAF and MEK inhibitors to report three years of follow-up survival data in two Phase III studies in BRAFv600+ 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 (NSCLC). *Tafinlar* has a Breakthrough Therapy designation from the FDA for treatment of NSCLC patients with BRAF V600E mutations who have received at least one prior line of platinum-containing chemotherapy. In July 2015, the combination therapy *Tafinlar + Mekinist* also received Breakthrough Therapy designation from the FDA for NSCLC patients with BRAF V600E mutations. In November 2016, the FDA granted Priority Review to *Tafinlar + Mekinist* for the treatment of BRAF positive NSCLC, as detected by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy.

*Tasigna* (nilotinib) is a selective tyrosine-kinase inhibitor that inhibits the BCR-ABL protein produced by the Philadelphia chromosome, which is found in most people who have chronic myeloid leukemia (CML). Novartis has an ongoing global clinical trial program to evaluate the potential for Philadelphia chromosome positive (Ph+) CML patients to maintain deep molecular response after stopping nilotinib. ENESTfreedom, ENESTop, ENESTgoal, and ENESTpath are designed to evaluate the feasibility of stopping treatment, and achieving successful treatment-free remission in patients with Ph+ CML in the chronic phase and deep molecular response on nilotinib. Data from ENESTfreedom and ENESTop were presented at major US and European medical congresses in 2016. An application was filed with the EMA for the inclusion of the ENESTfreedom and ENESTop data in the Summary of Product Characteristics of *Tasigna*.

UNR844 is a potential first-in-class topical treatment in development for presbyopia. 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 with enhanced antibody-dependent cell-mediated cytotoxicity against B cells. VAY736 is in Phase II development for the treatment of primary Sjoegren'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.

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.

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*Zykadia* (ceritinib) is a potent and highly selective oral anaplastic lymphoma kinase (ALK) inhibitor that is in development for ALK positive (ALK+) cancers. Two Phase III clinical trials comparing ceritinib with chemotherapy in treatment-naïve and in previously-treated non-small cell lung cancer (NSCLC) patients have demonstrated a statistically significant and clinically meaningful benefit. Results from the Phase III ASCEND-4 study found that patients with ALK+ advanced NSCLC treated with first-line Zykadia had a median progression-free survival of 16.6 months, compared to 8.1 months in patients treated with standard first-line chemotherapy with maintenance. The study findings were presented in December 2016 at the World Conference on Lung Cancer. Results from the randomized Phase III ASCEND-5 study of *Zykadia* were presented at the European Society for Medical Oncology (ESMO) congress in October 2016. The ASCEND-5 study assessed median progression-free survival (PFS) in patients previously treated with crizotinib and one or two prior regimens of cytotoxic chemotherapy (including platinum doublet), who then received *Zykadia* or standard chemotherapy. There was a statistically significant and clinically meaningful improvement in median PFS for patients taking *Zykadia* versus chemotherapy as determined by a blinded independent review committee. In addition, updated results from the Phase II ASCEND-3 study were presented at the ESMO congress in October 2016 which demonstrated that patients with ALK+ NSCLC taking *Zykadia* as their first ALK inhibitor (post-chemotherapy) had a median PFS of 18.4 months. In December 2016, applications were submitted in the US and EU for *Zykadia* as a first-line treatment for patients with ALK+NSCLC based on the results of the ASCEND-4 trial.

***Projects Added To And Subtracted From The Development Table Since 2015***

| **Project/Product** | **Potential indication/ Disease area** | **Change** | **Reason** |
|---|---|---|---|
| ABL001 | Chronic myeloid leukemia | Now disclosed as chronic myeloid leukemia, 3rd line | |
| *Afinitor/Votubia* | Non-functioning GI and lung neuroendocrine tumors | Commercialized | |
| | Diffuse large B-cell lymphoma | Removed | Development discontinued |
| *Arzerra* | Chronic lymphocytic leukemia (extended treatment) | US: Commercialized<br>EU: Removed | Approved in US<br>Development discontinued in EU |
| | Chronic lymphocytic leukemia (relapse) | Commercialized | |
| ASB183 | Solid and hematological tumors | Removed | Development discontinued |
| BGJ398 | Solid tumors | Removed | Development discontinued |
| BKM120 | Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor resistant/mTOR naïve, 2nd line (+ fulvestrant) | Removed | Development discontinued |
| | Metastatic breast cancer, hormone receptor-positive, aromatase inhibitor and mTOR inhibitor | Removed | Development discontinued |

| | | | |
|---|---|---|---|
| | resistant, 3rd line (+ fulvestrant) | | |
| | Solid tumors | Removed | Development discontinued |
| BYL719 | Solid tumors | Removed | Development discontinued |
| BYM338 | Sporadic inclusion body myositis | Removed | Development discontinued |

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| Project/Product | Potential indication/ Disease area | Change | Reason |
|---|---|---|---|
| *Cosentyx* | Psoriatic arthritis head-to-head study vs. adalimumab | Added | Entered confirmatory development |
| | Ankylosing spondylitis head-to-head study vs. adalimumab | Added | Entered confirmatory development |
| EGF816 | Solid tumors | Removed | Development discontinued |
| *Exjade* film-coated tablet (FCT) | Iron overload | Commercialized | |
| FCR001 | Renal transplant | Removed | Development discontinued |
| FTY720 | Pediatric multiple sclerosis | Added | Pediatric indication disclosed |
| *Gilenya* | Chronic inflammatory demyelinating polyradiculoneuropathy | Removed | Development discontinued |
| HSC835 | Stem cell transplantation | Removed | Development discontinued |
| INC280 | Non-small cell lung cancer EGFR mutation | Added | Entered confirmatory development |
| *Ilaris* (ACZ885) | Hereditary periodic fevers | Now disclosed as periodic fever syndromes | |
| *Jakavi* | Early myelofibrosis | Added | Entered confirmatory development |
| | Graft-versus-host disease | Added | Extended licensing agreement with Incyte Corporation |
| LAM320 | Multi-drug resistant tuberculosis | Added | Entered confirmatory development |
| LEE011 | Hormone receptor-positive, HER2-negative breast cancer (adjuvant) | Added | Entered confirmatory development |
| | Solid tumors | Removed | Development discontinued |

| | | | |
|---|---|---|---|
| LIK066 | Weight loss | Added | Entered confirmatory Development |
| LJM716 | Solid tumors | Removed | Development discontinued |
| *Lucentis* | Choroidal neovascularization secondary to conditions other than age-related macular degeneration and pathologic myopia | Commercialized | |
| pegpleranib | Neovascular age-related macular degeneration | Removed | Development in combination with *Lucentis* discontinued |

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| Project/Product | Potential indication/ Disease area | Change | Reason |
|---|---|---|---|
| PKC412 | Aggressive systemic mastocytosis | Now disclosed as advanced systemic mastocytosis | |
| | Acute myeloid leukemia (FLT3 wild type) | Added | Entered confirmatory development |
| *Promacta/Revolade* | Pediatric immune thrombocytopenia | Commercialized | |
| | Severe aplastic anemia, 1st line | Added | Entered confirmatory development |
| QAX576 | Allergic diseases | Removed | Development discontinued |
| QBW251 | Cystic fibrosis | Added | Entered confirmatory Development |
| QGE031 | Chronic spontaneous urticaria/ Inducible urticaria | Now disclosed as chronic spontaneous urticaria/ chronic idiopathic urticaria | |
| RTH258 | Neovascular age-related macular degeneration | Added | Transferred from Alcon Division |
| | Diabetic macular edema | Added | Transferred from Alcon Division |
| SEG101 | Sickle cell disease | Added | Acquired with acquisition of Selexys Pharmaceuticals Corporation |
| UNR844 | Presbyopia | Added | Acquired with acquisition of Encore Vision, Inc. |
| *Votrient* | Renal cell carcinoma (adjuvant) | Removed | Development discontinued |
| ZPL389 | Atopic dermatitis | Added | Acquired with acquisition of Ziarco Group Limited |

**Principal Markets**

The Innovative Medicines Division sells products in approximately 155 countries worldwide. Net sales are generally concentrated in the US, Europe and Japan. However, sales from Emerging Growth Markets have

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become increasingly important to us. The following table sets forth the aggregate 2016 net sales of the Innovative Medicines Division by region:

| Innovative Medicines | 2016 Net sales to third parties | |
|---|---|---|
| | $ millions | % |
| Europe | 11,217 | 34 |
| United States | 10,897 | 33 |
| Asia, Africa, Australasia | 7,696 | 24 |
| Canada and Latin America | 2,752 | 9 |
| **Total** | **32,562** | **100** |
| Of which in Established Markets* | 24,416 | 75 |
| Of which in Emerging Growth Markets* | 8,146 | 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. Sales of certain ophthalmic pharmaceutical products, including those for allergies, anti-inflammation and dry eye, are subject to seasonal variation.

**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, 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.

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.

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**Marketing and Sales**

The Innovative Medicines Division serves customers with 3,234 field force representatives in the US, and an additional 20,965 in the rest of the world, as of December 31, 2016, 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 now the largest single payor for healthcare services in the US. In addition, both commercial and government sponsored managed care organizations continue to be one of the largest groups of payors for healthcare services in the US. In other territories, national health services are often the only significant payor for healthcare services. In an effort to control prescription drug costs, almost all managed care organizations and national health services use formularies that list specific drugs that may be reimbursed, and/or the level of reimbursement for each drug. Managed care organizations and national health services also increasingly utilize various cost-benefit analyses to determine whether or not newly-approved drugs will be added to a formulary and/or the level of reimbursement for that drug, and whether or not to continue to reimburse existing drugs. We have dedicated teams that actively seek to optimize formulary positions for our products.

**Competition**

The global pharmaceutical market is highly competitive, and we compete against other major international corporations which 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 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

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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 2016 Compared to 2015 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 2015 Compared to 2014 Innovative Medicines Research and development."

***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, and three other US locations, Singapore and China, more than 6,000 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. Research platforms such as the Center for Proteomic Chemistry are headquartered at the NIBR site in Basel, Switzerland. In addition, the Novartis Institute for Tropical Diseases, the Friedrich Miescher Institute, and the Genomics Institute of the Novartis Research Foundation focus on basic genetic and genomic research as well as research into diseases of the developing world such as malaria, dengue and African sleeping sickness.

All drug candidates are taken to the clinic via "proof-of-concept" trials to enable 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 March 2016, Dr. Mark Fishman, President of NIBR, reached his contractual retirement age and retired. Dr. James E. Bradner, a physician-scientist from Dana Farber Cancer Institute and Harvard Medical School succeeded Dr. Fishman in that role.

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) will move research programs and operations from Singapore to Emeryville, California, where it will be co-located with our infectious diseases research team. We also plan to complete the exit of all internal non-human primate research. These changes will result in the

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closure of a biologics group in Shanghai, China and a team focused on non-human primate research in Fort Worth, Texas. We also plan to close ESBATech, a biologics group in Schlieren, Switzerland, subject to all appropriate consultation.

***Development program***

Effective July 1, 2016, we established a Global Drug Development (GDD) organization to oversee 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 portfolio management. The new 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 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.

**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

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IMB is chaired by our Global Head of Drug Development and Chief Medical Officer and has representatives from Novartis senior management, as well as experts from a variety of 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 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.

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 is subject to customary closing conditions, including regulatory approval.

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 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. Upon exercise of the option, Novartis will obtain an exclusive, worldwide license to develop and commercialize products containing emricasan. The exercise of the option is subject to customary closing conditions, including regulatory approval.

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.

In November 2016, we acquired Selexys Pharmaceuticals Corporation and SEG101 (crizanlizumab, formerly SelG1), 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 plan 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 receives 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.

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

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

In 2012, Novartis and the University of Pennsylvania (Penn) announced an exclusive global research and development collaboration to develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies for the treatment of cancers. The research component of this collaboration focuses on accelerating the discovery and development of additional therapies using CAR immunotherapy. In September 2014, as part of its alliance with Novartis, Penn announced plans for the construction of the Center for Advanced Cellular Therapeutics (CACT) on the Perelman School of Medicine campus in Philadelphia, Pennsylvania. The CACT opened in February 2016 and 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 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.

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

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

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

***European Union***

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

Under the Centralized Procedure, applications are made to the EMA for an authorization which is valid for the European Community. The Centralized Procedure is mandatory for all biotechnology products and for new chemical entities in cancer, neurodegenerative disorders, diabetes and AIDS, autoimmune diseases or other immune dysfunctions and optional for other new chemical entities or innovative medicinal products or in the interest of public health. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's safety, efficacy and quality, then the company may submit an application to the EMA. The EMA then receives and validates the application, and appoints a Rapporteur and Co-Rapporteur to review it. The entire review cycle must be completed 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)

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the application is done simultaneously in selected or all Member States if a medicinal product has not yet been authorized in a Member State. During the DCP, the RMS drafts an Assessment Report within 120 days. Within an additional 90 days the Concerned Member States (CMS) review the application and can issue objections or requests for additional information. On Day 90, each CMS must be assured that the product is safe and effective, and that it will cause no risks to the public health. Once an agreement has been reached, each Member State grants national marketing authorizations for the product.

After the Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMA (if approval was granted under the Centralized Procedure) or to the National Health Authorities (if approval was granted under the DCP or the MRP). In addition, several pharmacovigilance measures must be implemented and monitored including Adverse Event collection, evaluation and expedited reporting and implementation, as well as update Risk Management Plans. For some medications, post approval studies (Phase IV) may be required to complement available data with additional data to evaluate long term effects (called a Post Approval Safety Study, or PASS) or to gather additional efficacy data (called a Post Approval Efficacy Study, or PAES).

European Marketing Authorizations have an initial duration of five years. After this time, the Marketing Authorization may be renewed by the competent authority on the basis of re-evaluation of the risk/benefit balance. Once renewed the Marketing Authorization is valid for an unlimited period. Any Marketing Authorization which is not followed within three years of its granting by the actual placing on the market of the corresponding medicinal product ceases to be valid.

***Japan***

In Japan, applications for new products are made through the Pharmaceutical and Medical Devices Agency (PMDA). Once an NDA is submitted, a review team is formed consisting of specialized officials of the PMDA, including chemistry/manufacturing, non-clinical, clinical and biostatistics. While a team evaluation is carried out, a data reliability survey and Good Clinical Practice/Good Laboratory Practice/Good Manufacturing Practice inspection are carried out by the Office of Conformity Audit and Office of GMP/GQP Inspection of the PMDA. Team evaluation results are passed to the PMDA's external experts who then report back to the PMDA. After a further team evaluation, a report is provided to the Ministry of Health, Labor and Welfare (MHLW), which makes a final determination for approval and refers this to the Council on Drugs and Foods Sanitation which then advises the MHLW on final approvability. Marketing and distribution approvals require a review to determine whether or not the product in the application is suitable as a drug to be manufactured and distributed by a person who has obtained a manufacturing and distribution business license for the type of drug concerned and confirmation that the product has been manufactured in a plant compliant with Good Manufacturing Practices.

Once the MHLW has approved the application, the company can make the new drug available for physicians to prescribe. After that, the MHLW lists its national health insurance price within 60 days (or 90 days) from the approval, and physicians can obtain reimbursement. For some medications, the MHLW requires additional post-approval studies (Phase IV) to evaluate safety, effects and/or to gather information on the use of the product under special conditions. The MHLW also requires the drug's 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.

***Direct efforts to control prices***

*United States.* In the US, as a result of the Patient Protection and Affordable Care Act (ACA), the recurring focus on deficit reduction, and public pressure on elected officials based on recent price increases

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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 2016 predicted that the projected 5-year average growth in per capita Medicare program spending is likely to exceed a specified target level in 2017. If the Chief Actuary for CMS determines that the projected 5-year average growth rate exceeds the target, the IPAB would then develop savings proposals in 2018 based on a savings target set by the Chief Actuary, to be implemented in 2019. There is also a possibility that government officials will continue to search for additional ways to reduce or control prices, including state legislation mandating drug price controls, which could include limits on annual price increases or maximum price levels.

*Europe.* In Europe, our operations are subject to significant price and marketing regulations. Many governments are introducing healthcare reforms in a further attempt to curb increasing healthcare costs. In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general in the EU, particularly with regard to prescription drugs, has become very intense. Increasingly strict analyses are applied when evaluating the entry of new products, and, as a result, 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, including new EU Member States, further impacting individual EU Member State pricing.

*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 currently undertaking a healthcare reform initiative with a goal of sustaining the universal coverage of the National Health Insurance program, and is addressing the efficient use of drugs, including promotion of generic use. Meanwhile, the government tentatively initiated a premium system which basically maintains the price of patented drugs for unmet medical needs in order to promote innovative new drug creation and the solution of the unapproved indication issue. The continuance of this system will be reviewed as a part of price reforms in 2018. In December 2016, the Japanese government announced basic reform principles for fundamental reforms of the drug pricing system in 2018. These include an increase in the frequency of price cuts from every other year to annually, beginning after the next regular price revision scheduled for April 2018. The government's practice of mandating additional price decreases for specific products will continue.

*Rest of World.* Many other countries around the world are also taking steps to control prescription drug prices. For example, in 2016, China, one of our most important emerging growth markets, organized national price negotiations for certain products directly linked to local drug reimbursement without further bidding, which will apply nationwide both in public and military hospitals, with drug price reductions of more than 50% 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. In addition, the Colombian government has taken 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, and we are contesting its appropriateness with respect to *Glivec* in Colombia, 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, many governments and private medical care providers, such as Health Maintenance Organizations, have instituted reimbursement schemes that favor the substitution of

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generic pharmaceuticals for more expensive brand-name pharmaceuticals. In the US, generic substitution statutes have been enacted by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug instead of an original patented drug. Other countries have similar laws, including numerous European countries. We expect that the pressure for generic substitution will continue to increase. In addition, the US, EU and other jurisdictions are increasingly developing laws and regulations encouraging the development of biosimilar versions of biologic drugs, which can also be expected to have an impact on pricing.

***Cross-Border Sales***

Price controls in one country can also have an impact in other countries as a result of cross-border sales. In the EU, products which we have sold to customers in countries with stringent price controls can in some instances legally be re-sold to customers in other EU countries with less stringent price controls at a lower price than the price at which the product is otherwise available in the importing country. In North America, products which we have sold to customers in Canada, which has relatively stringent price controls, are sometimes re-sold into the US, again at a lower price than the price at which the product is otherwise sold in the US. Such imports from Canada and other countries into the US are currently illegal. Given the increased focus on pharmaceutical prices in the US, members of the US Congress 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.

**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(s) 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 will improve patient outcomes when administered certain drugs, as well as assays, research tools and other techniques used to identify new drugs. The protection offered by such patents extends for varying periods depending on the grant and duration of patents in the various countries or region. The protection afforded, which may vary from country to country, depends upon the type of patent and its scope of coverage.

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

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***United States***

***Patents***

In the US, a patent issued for an application filed today will receive a term of 20 years from the application filing date, subject to potential 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.

***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

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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 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 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

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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 patent protection for pharmaceutical products, or on the extent to which such protections may be enforced. 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, grant or authorization of a patent, patent term extension, marketing exclusivity or data protection means grant or authorization in at least one country and possibly pending in others. Marketing exclusivities and patent term extensions include orphan drug exclusivity (ODE), pediatric exclusivity (PE), patent term extension (PTE) and SPC.

For each 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. 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."

***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).

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There is generic competition in the US, EU and Japan. In the US, Novartis has resolved patent litigation with certain generic manufacturers. An additional generic manufacturer has filed an ANDA challenging the US polymorphic compound form patent; the automatic 30-month stay preventing FDA approval will expire in March 2018. Novartis is taking steps in some EU countries to enforce the polymorphic compound form 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.

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

*Sandostatin* 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); patent on antioxidant (2019); patent on antioxidant (2019), PE (2020); patent on TSC/SEGA use (2022), PE (2022); patent on breast cancer use (2022), PE (2022); patent on renal cell carcinoma use (2025), PE (2026); patent on pancreatic neuroendocrine tumor use (2028); 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 pancreatic neuroendocrine tumor use (2026); ODE (*Votubia*) (2021). Japan: Patent on compound (2013), PTE (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); ODE (tuberous sclerosis) (2022); RDP (2018).

There is currently no generic competition in the US, EU or Japan. In the US, generic manufacturers have filed ANDAs challenging several patents; the earliest automatic 30-month stay preventing FDA approval will expire in April 2018. The US compound patent is being challenged in IPR proceedings in the USPTO.

*Exjade* and *Jadenu.*

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

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

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

*Tafinlar* and *Mekinist.*

*Tafinlar*: US: Patent on compound (2030); RDP (2018); ODE (2020). EU: RDP (2023). Japan: Patent on compound (2029). There is currently no generic competition in the US, EU or Japan.

*Mekinist*: US: Patent on compound (2025), pending PTE (2027); patent on method of use (2025); patent on formulation (2032); RDP (2018); ODE (2020). EU: Patent on compound and method of use (2025),

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SPC (2029); RDP (2025). Japan: Patent on compound (2025); patent on method of use (2025); patent on formulation (2031). There is currently no generic competition in the US, EU or Japan.

Use of *Mekinist* with *Taflinar* or *Taflinar* with *Mekinist*: US: Patent on use of *Tafinlar* and *Mekinist* (2030); RDP (2017); ODE 2021. EU: RDP (2025). Japan: Patent on use of *Tafinlar* and *Mekinist* (2030). There is currently no generic competition in the US, EU or Japan.

*Promacta/Revolade.* US: Patent on compound (2021), PTE (2022), PE (2023); patent on salt form (2025); patent on formulation (2027). EU: Patent on compound (2021), SPC (2025); patent on salt form (2023); patent on formulation (2027); RDP (2020). Japan: Patent on compound (2021), PTE (2025); patent on salt form (2023); patent on formulation (2027); RDP (2018). There is currently no generic competition in the US, EU or Japan. The EU formulation patent is being opposed in the EPO.

*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 compositions for medical uses (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.

***Novartis Pharmaceuticals Business Unit***

*Ophthalmology*

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

*Duotrav, Travatan* and *Travatan Z.*

*Duotrav.* EU: Patent on methods of use (2014), SPC (2016), PE (2017); two 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 currently no generic competition in the EU or Japan. In the EU, the formulation patents are being opposed in the EPO.

*Travatan.* EU: Patent on method of use (2014), SPC (2016), PE (2017); two patents on formulations (2029). *Travatan* is not marketed in the US or Japan. There is generic competition in some EU countries. In the EU, the formulation patents are being opposed in the EPO.

*Travatan Z.* US: Three patents on formulations (2027(2), 2029). Japan: Patent 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.

*Systane Ultra, Systane* Original*, Systane Balance* and *Systane* Hydration.

*Systane Ultra.* US: Three patents on formulation (2017, 2018, 2028). EU: Two patents on formulation (2017, 2018). Japan: Three patents on formulation (2017, 2018, 2029). There is currently no generic competition in the US, EU or Japan.

*Systane* Original. US: Patent on formulation (2018). EU: Patent on formulation (2018). Japan: Patent on formulation (2018). There is currently no generic competition in the US, EU or Japan.

*Systane Balance.* US: Patent on formulation (2018). EU: Two patents on formulation (2018, 2030). Japan: Two patents on formulation (2018, 2030). There is currently no generic competition in the US, EU or Japan.

*Systane* Hydration. US: Two patents on formulation (2018, 2024). EU: Two patents on formulation (2018, 2024). Japan: Two patents on formulation (2018, 2024). There is currently no generic in the US, EU or Japan.

*Patanol, Pataday* and *Pazeo.*

*Patanol.* EU: Patent on method of use (2016), SPC (2017). Japan: Patent on method of use (2016), PTE (2021). There is generic competition in the US and some EU countries. There is currently no generic

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competition in Japan. The Japanese method of use patent is being challenged in the Japanese Patent Office.

*Pataday.* US: Patent on formulation (2022), PE (2022); patent on formulation (2023), PE (2024). *Pataday* is not marketed in the EU or Japan. There is currently no generic competition in the US. In the US, Novartis has resolved patent litigation with certain generic manufacturers. In the US, an additional generic manufacturer has filed an ANDA challenging the formulation patents; the automatic 30-month stay preventing FDA approval will expire in April 2019.

*Pazeo.* US: Patent on formulation (2032); New Product Exclusivity, PE (2018). *Pazeo* is not marketed in the EU or Japan. There is currently no generic competition in the US. In the US, generic manufacturers have filed ANDAs challenging the formulation patent; the earliest automatic 30-month stay preventing FDA approval will expire in May 2018.

*Neuroscience*

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

*Immunology and Dermatology*

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

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

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

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

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

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

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*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.

*Ultibro Breezhaler/Utibron Neohaler, Onbrez Breezhaler/Arcapta Neohaler* and *Seebri Breezhaler/Neohaler.*

*Ultibro Breezhaler/Utibron Neohaler.* US: Patent on compound (2020), PTE (2025); three patents on methods of use (2021); patent on device (2025); RDP (2018). EU: Patent on compound (2020), SPC (2024); patent on device (2025); patent on method of use (2021), SPC (2026); RDP (2023). Japan: Patent on compound (2020), PTE (2025); patent on device (2025); patent on method of use (2021); RDP (2019). There is currently no generic competition in the US, EU or Japan.

*Onbrez Breezhaler/Arcapta Neohaler.* US: Patent on compound (2020), PTE (2025); patent on device (2025). EU: Patent on compound (2020), SPC (2024); patent on device (2025); RDP (2019). Japan: Patent on compound (2020), PTE (2025); patent on device (2025); RDP (2019). There is currently no generic competition in the US, EU or Japan.

*Seebri Breezhaler/Neohaler.* US: Patent on device (2025); three patents on uses (2021); RDP (2018). EU: Patent on formulation (2027); patent on device (2025); patent on use (2021), SPC (2026); RDP (2022). Japan: four patents on formulations (2025 (2), 2026 (2)); patent on device (2027); patent on use (2021); RDP (2020). There is currently no generic competition in the US, EU or Japan.

*Cardio-Metabolic*

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

*Entresto.* US: Patents on combination (2023); patents on complex (2026, 2027); RDP (2020). EU: Patent on combination (2023), SPC (2028); patent on complex (2026), SPC (2030); patents on formulation (2028 (2)); RDP (2025). Japan: Patent on combination (2023); patent on complex (2026); patent on formulation (2028). There is currently no generic competition in the US, EU or Japan. The EU complex patent and the EU formulation patent are being opposed in the EPO.

*Established Medicines*

*Diovan* and *Co-Diovan/Diovan HCT. Diovan*: US: Patent on formulation (2017), PE (2017). There is generic competition in the US, EU and Japan. *Co-Diovan/Diovan HCT*: US: Patent on formulation (2017), PE (2017). Japan: Patent on formulation (2017). There is generic competition in the US, EU and Japan.

*Exforge* and *Exforge HCT.*

*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). 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.

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

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*Exelon and Exelon Patch.*

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

*Exelon Patch*: US: Patents on formulations (2019). EU: Patent on formulation (2019); patent on transdermal dosage regime (2026). Japan: Patent on formulation (2019); RDP (2019). There is generic competition in the US and in most EU countries. There is currently no generic competition in Japan. We are taking steps in several countries to enforce our EU transdermal dosage regime patent against generic competitors. In the EU, we have resolved patent litigation with certain generic manufacturers. The EU transdermal dosage regime patent is being opposed in the EPO and several national patents are being challenged in national courts. In the US, Novartis has resolved patent litigation with certain generic manufacturers. The US formulation patents are being challenged in an IPR proceeding in the USPTO.

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

***Compounds in Development***

We provide the following information 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.

LEE011. US: Three patents on compound (2028, 2030, 2031); two patents on methods of use (2029); patent on salt (2031). EU: Patent on compound (2029); patent on methods of use (2029). Japan: Two patents on compound (2027, 2029); two patents on methods of use (2027, 2029).

PKC412. US: Three patents on methods of use (2022, 2024, 2030). EU: Two patents on methods of use (2022, 2024); patent on formulation (2020). Japan: Two patents on methods of use (2022, 2024); patent on formulation (2020).

**SANDOZ**

Our Sandoz Division is a global leader in generic pharmaceuticals and biosimilars and sells products in more than 150 countries. In 2016, 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 dermatology, respiratory, oncology and ophthalmics, cardiovascular, metabolism, central nervous system, pain, gastrointestinal and hormonal therapies, 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.

Sandoz products reached more than 500 million patients worldwide in 2016 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.

Examples of marketed products in the Sandoz portfolio include multiple sclerosis treatment *Glatopa* (glatiramer acetate injection) 20mg/mL, respiratory inhaler therapy *AirFluSal Forspiro* (fluticasone salmeterol), and pain medication fentanyl, which is delivered using a

transdermal patch.

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Sandoz also has a strong and continued strategic focus on biosimilars, which it began developing in 1996 and today sells in more than 60 countries. Sandoz is the market leader in biosimilars and all three of its biosimilars continue to demonstrate strong growth in their respective categories *Omnitrope*, a human growth hormone*Binocrit,* an erythropoiesis-stimulating agent used to treat anemia; and filgrastim for neutropenia under the brand names *Zarzio* outside the US and *Zarxio* in the US.

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

Our biosimilar *Binocrit* (epoetin alfa) was approved in the EU for a new route of administration, based on data from a study in pre-dialysis and dialysis patients with anemia associated with chronic kidney disease. Filings were accepted in the EU in 2016 for our pegfilgrastim and rituximab biosimilars. We plan to make regulatory filings for adalimumab in the US and EU, rituximab in the US, and infliximab in the EU in 2017. We received a complete response letter for pegfilgrastim from the from FDA in June 2016, and plan to submit additional data for pegfilgrastim to the FDA in 2018.

According to IMS Health, Sandoz holds the global number one position in sales of biosimilars and of generic anti-infectives, ophthalmics and transplantation medicines. In addition, Sandoz holds leading global positions in key therapeutic areas such as generic injectables, dermatology, respiratory, cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

In 2016, key product launches in the US included amphetamine salts extended release (Shire's Adderall XR®), linezolid solution for infusion/injection (Pfizer's Zyvox®), mometasone furoate (Merck & Co. Inc.'s Nasonex® nasal spray), and oxiconazole nitrate (*Oxistat*).

In 2016, key product launches in various European countries included imatinib mesylate (*Glivec*), *ACC* solution for injection, buprenorphine 4 and 7 day transdermal therapeutic system, matrix patch (Mundipharma's BuTrans®, Norspan®), calcipotriol bethametasone ointment (Leo Pharma's Dovobet®), fluticasone salmeterol powder dose inhaler (GSK's Seretide®) and linezolid film coated tablet (Pfizer's Zyvoxid®).

Following an internal reorganization announced on January 27, 2016, nineteen mature products were transferred from our Innovative Medicines Division (formerly named the Pharmaceuticals Division) to the Retail Generics franchise of Sandoz. In compliance with IFRS, Novartis updated its segment financial information to reflect these transfers, both for the current and prior years, to aid comparability of year-on-year results. As a result, all comparisons of divisional results from 2016, 2015 and 2014 in this Form 20-F reflect this new divisional structure.

Effective as of April 1, 2016, operational control for the Novartis Malaria Initiative was transferred from our Innovative Medicines Division to Sandoz. In addition, Sandoz has assumed operational responsibility for Novartis Access, launched in September 2015, which comprises an initial portfolio of fifteen medicines to treat chronic diseases in low and middle income countries. The portfolio, the majority of which are Sandoz medicines, addresses cardiovascular diseases, 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. The existing Sandoz tuberculosis business, as well as Novartis Social Business, which includes the Arogya Parivar "Healthy Families" initiative, is also operationally managed by the same unit, under the Sandoz Global Commercial Operations function.

**New Products**

Sandoz launched a number of important products in various countries in 2016, including:

*ACC* solution for injection

Amphetamine salts extended release (Shire's Adderall XR®)

Buprenorphine 4 and 7 day transdermal therapeutic system, matrix patch (Mundipharma's BuTrans®, Norspan®)

Calcipotriol bethametasone ointment (Leo Pharma's Dovobet®)

Esomeprazole *MUT* (Astra Zeneca's Nexium®)

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Fluticasone salmeterol powder dose inhaler (GSK's Seretide®)

Linezolid solution for infusion/injection (Pfizer's Zyvox®)/ Linezolid film coated tablet (Pfizer's Zyvoxid®)

Mometasone furoate (Merck & Co. Inc.'s Nasonex® nasal spray)

Oxiconazole nitrate (*Oxistat*)

**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 |
| Fentanyl | various | Pain treatment |
| Cyclophosmamide | Endoxan® | Breast, ovarian and non-small cell cancer treatment |
| Levothyroxine sodium | Synthroid®; Levoxyl® | Hypothyroidism 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 |

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

***Biopharmaceuticals***

| Product | Originator Drug | Description |
|---|---|---|
| *Binocrit* and Epoetin alfa *Hexal* | Eprex®/Erypo® | Recombinant protein used for anemia |
| *Omnitrope* | Genotropin® | Recombinant human growth hormone |
| *Zarzio*, *Zarxio* and Filgrastim *Hexal* | Neupogen® | Recombinant protein used in oncology |
| *Glatopa* | Copaxone® 20 mg | Multiple sclerosis treatment |

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**Biosimilars in Phase III Development and Registration**

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

| Project/product | Common name | Mechanism of action | Potential indication/ indications | Therapeutic areas | Route of administration | Current phase |
|---|---|---|---|---|---|---|
| GP1111 | infliximab | TNF-α inhibitor | Inflammatory bowel disease, rheumatoid arthritis and plaque psoriasis (same as originator) | Immunology | Intravenous | EU: III |
| 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: Registration US: III |
| GP2015 | etanercept | TNF-α inhibitor | Arthritides (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis), plaque psoriasis and others (same as originator) | Immunology | Subcutaneous | EU: Registration US: Approved |
| GP2017 | adalimumab | TNF-α inhibitor | Arthritides (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis), plaque psoriasis and others (same as originator) | Immunology | Subcutaneous | III |
| HX575 | epoetin alfa | Erythropoiesis-stimulating agent | Anemia in chronic kidney disease, chemotherapy-induced anemia and others (same as originator) | Oncology and Nephrology | Subcutaneous and intravenous | US: III |
| LA-EP2006 | pegfilgrastim | Pegylated granulocyte colony-stimulating factor | Chemotherapy-induced neutropenia and others (same as originator) | Oncology | Subcutaneous | III[1][2] |

(1) Withdrawal of EU filing in January 2017 with planned re-filing in 2017.

(2) Resubmission planned for 2018 to address FDA complete response letter.

**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 2016 net sales of Sandoz by region:

| Sandoz | 2016 Net Sales to third parties | |
|---|---|---|
| | $ millions | % |
| Europe | 4,354 | 43 |
| United States | 3,708 | 37 |
| Asia, Africa, Australasia | 1,418 | 14 |
| Canada and Latin America | 664 | 6 |
| **Total** | **10,144** | **100** |
| Of which in Established Markets* | 7,580 | 75 |
| Of which in Emerging Growth Markets* | 2,564 | 25 |

* 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.

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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, 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.

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.

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 are related to deficiencies in current good manufacturing practice (cGMP) for finished pharmaceuticals. The Warning Letter did not contain any new issues in addition to the 483 observations issued following the August 2014 inspection. Sandoz plans to continue to collaborate with the FDA to resolve the Warning Letter observations.

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

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

**Marketing and Sales**

Sandoz sells a broad portfolio of generic pharmaceutical 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 products, such as products sold by our Retail Generics franchise, for patented pharmaceutical products. In the US, statutes have been enacted by virtually all states that permit or require pharmacists to substitute a less expensive generic product for the brand-name version of a drug that has been prescribed to a patient. Generic use is growing in Europe, but penetration rates in many EU countries (as a percentage of volume) remain well below those in the US.

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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 in recent years 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 (see " Regulation"). As a result, in many of these markets, including the US, our biosimilar products are marketed as branded competitors to the originator products.

**Competition**

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

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

**Development and Registration**

Effective July 1, 2016, development of Sandoz Biopharmaceuticals products is jointly overseen by Sandoz and 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, pharmaceutical products for which the patent and data exclusivity period has expired can be offered for sale at prices often much lower than those of products protected by patents and data exclusivity, which must recoup substantial basic research and development costs through higher prices over the life of the product's patent and data exclusivity period.

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

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

The 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 2016, Sandoz expensed $0.8 billion (on a core basis $0.8 billion) in product development, which amounted to 8% of the division's net sales. Sandoz expensed $0.8 billion (on a core basis $0.8 billion) and $0.8 billion (on a core basis $0.8 billion) in 2015 and 2014, respectively. Core results includes impairments, amortization and certain exceptional items. For additional information, see "Item 5. Operating and Financial Review and Prospects  5.A Operating Results  Non-IFRS Measures as Defined by Novartis  Core Results."

**Regulation**

***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 originator products, so long as the generic version could be shown in bioavailability studies to be of identical quality and purity, and to be therapeutically equivalent to the reference product.

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

In the EU, decisions on the granting of a marketing authorization are made either by the European Commission based on a positive recommendation by the EMA under the Centralized Procedure, or by a single Member State under the national or decentralized procedure. See "  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 medicine's innovator, without the need to conduct extensive Phase III clinical trials of its own. For all products that received a marketing authorization in the EU after late 2005, the Abridged Application can be submitted throughout the EU. However, the data submitted by the innovator in support of its application for a marketing authorization for the reference product will be protected for ten years after the first grant of marketing authorization in all Member States, and can be extended for an additional year if a further innovative indication has been authorized for that product, based on pre-clinical and clinical trials filed by the innovator that show a significant clinical benefit in comparison to the existing therapies.

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***Biosimilars***

The regulatory pathways for approval of biosimilar products are being developed and established in many countries of the world. A regulatory framework for the approval of biosimilars has been established in the EU, Japan, Canada and US, while the WHO has issued guidance. Sandoz has successfully registered and launched the first biosimilar (or biosimilar type) product in Europe, the US, Canada, Japan, Taiwan, Australia and many countries in Latin America and Asia. Sandoz has three approved biosimilar products in more than 60 countries, and is the first company to secure approval for and launch a biosimilar under the US biosimilar pathway, which 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 originator product in terms of safety, efficacy and quality through an extensive comparability exercise, based on strict guidelines set by the authorities. Regulators will only approve a biosimilar based on data which allows the regulators to conclude that there are no clinically meaningful differences between the reference product and the biosimilar.

Under the BPCIA, a biosimilar must be highly similar with no clinically meaningful differences compared to the reference product. Approval of a biosimilar in the US requires the submission of a BLA to the FDA, including an assessment of immunogenicity, and pharmacokinetics or pharmacodynamics. The BLA for a biosimilar can be submitted as soon as four years after the initial approval of the reference biologic, but can only be approved 12 years after the initial approval of the reference biologic. This pathway is still relatively new and some aspects remain untried, controversial and subject to ongoing litigation.

**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, which in some instances can be measured in terms of the competing company's profits.

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 sold in more than 145 countries. In 2016, the Alcon Division had consolidated net sales of $5.8 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 compliance with IFRS, Novartis updated its segment financial information to reflect these transfers, both for the current and prior years, to aid comparability of year-on-year results. As a result, all comparisons of divisional results from 2016, 2015 and 2014 in this Form 20-F reflect this new divisional structure.

In January 2017, we announced that we are 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. The review will be conducted during the course of 2017 and in a manner such that Alcon Division associates can fully

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focus on the unit's return to growth. The ophthalmic pharmaceutical portfolio is now fully integrated into our Innovative Medicines Division and will not be part of the review.

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 3D*, 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 (DAVS) to help improve visualization of the delicate tissues in the back of the eye.

In October 2014, Alcon acquired WaveTec Vision. This acquisition provided Alcon with the *ORA System*, the first commercialized intra-operative guidance system for cataract surgeons implanting IOLs. Alcon has integrated the *ORA System* into its existing Cataract Refractive Suite by Alcon.

In July 2014, Alcon entered into an agreement with Verily (formerly Google Life Sciences and Google [x]) to license its "smart lens" technology with the potential to address ocular conditions.

**Alcon Division Products**

*Surgical*

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

Alcon's Surgical portfolio includes the Cataract Refractive Suite by Alcon, a suite of equipment to help plan and perform some of the most challenging steps of cataract surgery with automation and precision. It is comprised of the *Centurion* vision system phacoemulsification technology platform; the *LenSx* laser, a femtosecond laser for increased precision and reproducibility for the corneal incision, capsulorhexis and lens fragmentation steps of the procedure; the *Verion* image guided system, an ocular surgical planning, imaging and guidance technology; the *ORA System*, an intra-operative guidance system for IOL implantation during cataract surgery; and the *LuxOR LX3* surgical microscope for greater visualization during surgery. Alcon's Surgical portfolio also includes the *Wavelight* refractive suite portfolio for LASIK treatments and other refractive procedures, including topography-guided procedures marketed under the *Contoura* name, the *Constellation* vision system for retinal operations, and the *Infiniti* vision system to perform cataract surgeries, which is the phacoemulsification platform introduced prior to the *Centurion* vision system. Alcon also offers the *AcrySof* family of intraocular lenses (IOLs) to treat cataracts, including monofocal, toric (astigmatism-correcting), and multifocal (presbyopia-correcting) options. The *AcrySof IQ PanOptix* presbyopia-correcting IOL is a hydrophobic acrylic trifocal IOL designed to provide exceptional functional vision from near to intermediate, in addition to providing distance vision comparable to that of a monofocal lens. In addition, Alcon provides advanced viscoelastics, surgical solutions, 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. 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.

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**New Products**

Alcon received a number of approvals and launched a number of products in 2016, including:

*CyPass* Micro-Stent, a micro invasive glaucoma surgery (MIGS) device, was launched in the US to treat patients with mild to moderate primary open-angle glaucoma in conjunction with cataract surgery.

*NGENUITY 3D* Visualization System was launched in the US and EU to provide surgeons improved visualization by combining 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 (DAVS).

*AcrySof IQ ReSTOR* 3.0D Toric IOL, was approved by the FDA to address presbyopia and preexisting astigmatism at the time of cataract surgery in adult patients who desire improved near, intermediate, and distance vision with an increased potential for spectacle independence.

*Air Optix* plus *HydraGlyde,* an innovation upgrade to silicon hydrogel contact lenses featuring *HydraGlyde* Moisture Matrix technology for longer lasting lens surface wettability, was launched in the US and EU.

*Dailies Total1* Multifocal contact lenses were launched in the US and EU to provide refractive correction with distance, intermediate and near vision for people with presbyopia.

***Key Marketed Products***

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

*Surgical*

| | |
|---|---|
| Cataract | *AcrySof* family of intraocular lenses includes: |
| | *AcrySof IQ* Monofocal, *AcrySof IQ Toric, AcrySof IQ ReSTOR* Multifocal, *AcrySof IQ ReSTOR* Toric*, AcrySof IQ ReSTOR* Multifocal Toric, and *AcrySof IQ PanOptix* Multifocal IOLs |
| | Cataract Refractive Suite by Alcon designed to streamline the cataract surgical procedure through surgical planning and execution |
| | *Centurion* vision system for phacoemulsification and cataract removal |
| | *Infiniti* vision system for phacoemulsification and cataract removal |
| | *LenSx* laser used for specific steps in the cataract surgical procedure |
| | *LuxOR* microscope used for ophthalmic surgical procedures |
| | *ORA System* intra-operative guidance system for use with cataract surgery |
| | *UltraSert* pre-loaded delivery system for intraocular lenses |
| | *Verion* imaged-guided system for use during cataract surgery |

| | |
|---|---|
| Vitreoretinal | *Constellation* vision system for vitreoretinal operations |
| | *Grieshaber* surgical instruments |
| | *NGENUITY 3D* high-resolution visualization system for vitreoretinal surgery |
| | *Purepoint* laser system and probes |
| | *Ultravit* vitrectomy probes |

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| | |
|---|---|
| Refractive | *WaveLight EX500* excimer laser for LASIK and PRK vision correction |
| | *Allegretto Wave Eye-Q* excimer laser for LASIK and PRK vision correction |
| | *WaveLight FS200* femtosecond laser for refractive surgery |
| Glaucoma | *CyPass* Micro-Stent for the treatment of glaucoma during cataract surgery |
| | *EX-PRESS* glaucoma filtration device |

In addition, Alcon provides advanced viscoelastic, surgical solutions, surgical packs and other disposable products for cataract and vitreoretinal surgery.

*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 |

***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.

*Surgical*

| Project/Product | Description | Product Category | Planned Submission | Current Phase |
|---|---|---|---|---|
| A02238 | Mid-tier phacoemulsification device | Cataract Equipment | US 2018<br>EU 2018 | Advanced<br>Advanced |
| *AcrySof IQ PanOptix* IOL | Trifocal IOL | Cataract Implant | US 2019 | Advanced |
| *AcrySof IQ PanOptix* Toric IOL | Trifocal IOL for astigmatism | Cataract Implant | US 2019 | Advanced |
| *AcrySof IQ ReSTOR 2.5D Toric IOL* | Multifocal IOL for astigmatism | Cataract Implant | US | Submitted |
| *Clareon* Monofocal IOL | Next-generation IOL | Cataract Implant | EU 2017 | Advanced |
| | | | US 2019 | Advanced |
| *CyPass* Micro-Stent | Micro-invasive glaucoma surgical device for implant during cataract surgery | Glaucoma Implant | EU 2017 | Advanced |

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*Vision Care*

| Project/Product | Description | Product Category | Planned Submission | Current Phase |
|---|---|---|---|---|
| A00717 | Daily disposable line extension | Contact Lens | EU 2018 | Advanced |
| | | | US 2018 | Advanced |
| A01660 | New daily disposable lens | Contact Lens | EU 2018 | Advanced |
| | | | US 2018 | 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 2016 net sales of the Alcon Division by region:

| Alcon | 2016 Net Sales to third parties | |
|---|---|---|
| | $ millions | % |
| Europe | 1,508 | 26 |
| United States | 2,512 | 43 |
| Asia, Africa, Australasia | 1,327 | 23 |
| Canada and Latin America | 465 | 8 |
| **Total** | **5,812** | **100** |
| Of which in Established Markets* | 4,630 | 80 |
| Of which in Emerging Growth Markets* | 1,182 | 20 |

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

Sales of the majority of our Alcon Division products are not subject to material changes in seasonal demand.

**Research and Development**

In 2016, our Alcon Division expensed $0.5 billion (on a core basis $0.5 billion) in research and development, which amounted to 9% of the Division's net sales. The Alcon Division expensed $0.5 billion (on a core basis $0.5 billion) and $0.5 billion (on a core basis $0.5 billion) in research and development in 2015 and 2014, respectively. Core results includes impairments, amortization and certain exceptional items. For additional information, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis Core Results."

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 refractive surgeries. The focus for the Vision Care franchise is on the research and development of new contact lens materials, coatings and designs to improve patient comfort, and on lens care solutions that provide the safety, disinfecting and cleaning power needed to help maintain ocular health.

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 Alcon's Surgical business franchise are manufactured at facilities located in the United States, Belgium, Switzerland, Ireland, Germany and Israel. Alcon's Vision Care business franchise production facilities are located in the US, Germany, Singapore, Malaysia and Indonesia.

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

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

**Marketing and Sales**

Our Alcon Division conducts sales and marketing activities around the world organized under five operating regions (Europe/Middle East/Africa, North America, Latin America/Caribbean, Asia and Russia, 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 and an integrated customer relationship management system is in place in many markets. Where applicable, we also rely on direct-to-consumer marketing campaigns to promote selected products or treatment options.

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. Lens care 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 typically competes with 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 provides 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 with us.

**Regulation**

Most of our Surgical and Vision Care products are regulated as medical devices in the US and the EU. These jurisdictions each have risk-based classification systems that determine the type of information that must be provided to the local 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))

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

**Intellectual Property**

We attach great importance to 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 the processes for manufacturing a product, and particular uses of a product.

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

### 4.C Organizational Structure

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

### 4.D Property, Plants and Equipment

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

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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.

Effective July 1, 2016, Novartis Technical Operations was formed to manage the production and supply chains of our Innovative Medicines and Sandoz Division products through a network of warehouse and distribution centers, 67 manufacturing sites, as well as through external suppliers. Our 16 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 |
|---|---|---|
| Kundl and Schaftenau, Austria | 480,000 | Production of biotechnological products, anti-infectives, active drug substances, product development |
| East Hanover, New Jersey | 400,000 | Innovative Medicines Division US headquarters, research and development |
| Barleben, Germany | 340,000 | Production of broad range of finished dosage forms |
| Basel, Switzerland St. Johann | 274,000 | Global Group headquarters, global Innovative Medicines Division headquarters, research and development, production of drug substances and drug intermediates |
| Fort Worth, Texas | 262,000 | Alcon Division headquarters, production, research and development for Alcon Vision Care, Surgical franchises |
| Changshu (Suzhou), China | 230,000 | Technical research, development and manufacturing of drug substances and drug intermediates |
| Cambridge, Massachusetts | 180,000 | 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 | Administrative offices for Innovative Medicines, Sandoz and Alcon |

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| Location | Size of Site (in square meters) | Major Activity |
|---|---|---|
| Holzkirchen, Germany | 72,300 | Sandoz Division headquarters, production of oral films, transdermal delivery systems, matrix patches, product development |
| Stein, Switzerland | 64,700 | Production of sterile vials, pre-filled syringes and ampoules, and of inhalation capsules, tablets and transdermals, and of active pharmaceutical ingredients |
| Grimsby, UK | 64,000 | Production of drug substances and drug intermediates |
| Puurs, Belgium | 55,000 | Production for ophthalmic medicines and Alcon Surgical franchise |
| Rueil-Malmaison, France | 48,200 | Administrative offices for Innovative Medicines and Alcon |
| Stryków, Poland | 45,000 | Production of broad range of bulk oral solid forms |
| Rudolfstadt, Germany | 44,000 | Development and production of respiratory technologies and ophthalmics |
| 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 | 27,498 | 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 |
| Princeton, New Jersey | 14,300 | Sandoz Division US headquarters |

To support the objectives of Novartis Technical Operations, we have initiated the network transformation project, under which we are reviewing our Innovative Medicines and Sandoz drug manufacturing network to ensure it can appropriately meet the future needs of the Group. The network transformation project replaces and complements the previously announced review of our manufacturing footprint. Among other things, as part of

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this initiative we plan to exit our Sandoz Division plant in Hicksville, New York by 2019. We expect the previously announced exit of our Sandoz Division site in Turbhe, India to be completed in 2017.

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. By the end of 2016, 17 new buildings had begun operations, eight of them laboratory buildings. The current phase of the long term redevelopment of our St. Johann site is largely complete. In addition, the Novartis Board of Directors approved planning for the next phase of the campus extension in line with the overall plan for the site. A large laboratory building has been planned for the northern end of the site, but construction is currently on hold. Through December 31, 2016, the total amount paid and committed to be paid on the Campus project is equivalent to $2.1 billion. Novartis expects to have spent more than the equivalent of $2.8 billion on the Campus project through the end of 2017. We intend to fund these expenditures from internally generated resources.

In 2007, NIBR opened a start-up facility for our new R&D center in Shanghai, China (CNIBR). In 2008, we broke ground on Phase 1 of a new facility that was originally to be home to approximately 400 R&D scientists and approximately 400 other Innovative Medicines Division personnel. In 2009, we announced that we would expand the scope of the site and invest $1 billion over the next five years to increase the size of our operations in Shanghai. Based on a re-evaluation of the site conducted in 2010, Phase one was extended by two buildings to fulfill the requirements for the cross-divisional Shanghai campus to house 800 offices and 400 laboratory work places. As of December 31, 2016, two laboratory buildings, four office buildings and one restaurant building were completed. Through December 31, 2016, the total amount paid on the CNIBR Project is equivalent to $800 million.

In 2010, we announced that we would build new laboratory and office space for NIBR in Cambridge, Massachusetts on an area of land close to the existing NIBR research facilities on Massachusetts Avenue. In 2011 we finalized design plans for the new buildings, received necessary zoning changes from the City of Cambridge and began preparing the site for construction. Construction began on the site in April 2012, and as of the end of 2016, these facilities were fully operational and all associates had moved into the new buildings. Through December 31, 2016, the total amount paid on the NIBR Project is $802 million.

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 $600 million. The new facility is planned to replace an older facility. In addition, Novartis plans to invest in new technologies and packaging facilities for pharmaceuticals at Stein. Stein is planned to be a technological competence center for both sterile and solid dosage form drugs. Through December 31, 2016, the total amount paid and committed to be paid on this project is equivalent to $559 million.

In 2012, we announced the planned construction of a new state-of-the-art biotechnology production site in Singapore with a planned investment of over $700 million. The new facility will focus on drug substance manufacturing based on cell culture technology. Ground was broken in February 2013 and construction was completed in the third quarter of 2015 for phase one of the project. We expect phase one of this project to be operational in 2017 and phase two in 2019. It will be co-located with the pharmaceutical production site based in Tuas, Singapore. In the future, Singapore is expected to be a technological competence center for both biotechnology and pharmaceutical manufacturing at Novartis. Through December 31, 2016, the total amount paid and committed to be paid on this project is equivalent to $546 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. The construction and equipment installation is now complete and equipment is currently undergoing validation. This project is expected to be completed in the second quarter of 2017. Through December 31, 2016, the total amount paid and committed to be paid on this project is $241 million.

The Alcon Division began an expansion of its Singapore facility in 2014 for contact lens manufacturing. The expansion is expected to add 16,000 square meters to the existing production lines. Through December 31, 2016, the total amount paid and committed to be paid on this project is equivalent to $95 million.

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**Environmental Matters**

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

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

See "Item 3. Key Information  Item 3.D Risk Factors  Environmental liabilities may adversely impact our results of operations." See also "Note 20. Provisions and other non-current liabilities" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**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, 2105 to CSL and our Animal Health Division was sold on January 1, 2015 to Lilly. For more detail on certain of these transactions see, "Item 10.C Material Contracts."

**Continuing Operations:**

Innovative Medicines (formerly named Pharmaceuticals): 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.

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 and Novartis Business Services.

The Novartis Institutes for BioMedical Research (NIBR) is the innovation engine of Novartis, which supports our Innovative Medicines Division and also collaborates with our Sandoz Division. More than 6,000 scientists and associates at NIBR conduct research into various disease areas at sites located in the US, Switzerland, Singapore and China. For more information about NIBR, see " Innovative Medicines Research and Development Research program," below.

Effective February 1, 2016, Mike Ball was appointed Division Head and CEO Alcon, and as a member of the Executive Committee of Novartis (ECN). Mike Ball succeeded Jeff George, who decided to leave Novartis.

Effective April 1, 2016, Alcon's Ophthalmic Pharmaceuticals products were transferred to our Innovative Medicines Division. At the same time, selected mature, non-promoted pharmaceutical products were shifted from our Innovative Medicines Division to Sandoz, which has proven experience in managing mature products successfully. Following these changes our Alcon Division is now focused on its Surgical and Vision Care franchises.

In May 2016, Novartis announced changes to focus its former Pharmaceuticals Division by creating two business units, Novartis Pharmaceuticals and Novartis Oncology, to form the Innovative Medicines Division. Effective July 1, 2016, Paul Hudson was appointed CEO, Novartis Pharmaceuticals and Bruno Strigini was appointed CEO, Novartis Oncology, both as members of the Executive Committee of Novartis. Mr. Hudson and Mr. Strigini report to Joseph Jimenez, CEO of Novartis.

In July 2016, we established the Global Drug Development (GDD) organization to oversee 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. Dr. Vas Narasimhan was appointed Global Head Drug Development and Chief Medical Officer, a newly created position in the ECN and reports to the CEO of Novartis. GDD includes approximately 10,000 associates worldwide.

In 2016, André Wyss, already a member of the ECN, Head Novartis Business Services (NBS) and Country President for Switzerland, was appointed President, Novartis Operations. In his new role, he assumed responsibility for the integrated Novartis Technical Operations (NTO) organization as well as for Global Public & Government Affairs, in addition to his previous responsibilities, and he continues to report to the CEO Novartis. NTO was established effective July 1, 2016, in order to centralize management of our manufacturing operations

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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 28,000 associates and 67 manufacturing sites across our Innovative Medicines and Sandoz Divisions.

NBS, our shared service organization, was also made a part of Novartis Operations in 2016. NBS 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 10,000 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 2016, Novartis continuing operations achieved net sales of $48.5 billion, while net income from continuing operations amounted to $6.7 billion. Of total net sales from continuing operations, $11.9 billion, or 25%, came from Emerging Growth Markets, and $36.6 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 2016 amounted to $9.0 billion ($8.5 billion excluding impairment and amortization charges).

Headquartered in Basel, Switzerland, our Group companies employed 118,393 full-time equivalent associates as of December 31, 2016. Our products are sold in approximately 155 countries around the world.

**Innovative Medicines Division**

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

In 2016, the Innovative Medicines Division accounted for $32.6 billion, or 67%, of Group net sales, and for $7.4 billion, or 85%, 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 dermatology, respiratory, oncology, ophthalmics, cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies, 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 2016, Sandoz accounted for $10.1 billion, or 21%, of Group net sales, and for $1.4 billion, or 17%, 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

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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 2016, Alcon accounted for $5.8 billion, or 12%, of Group net sales, and for $ 0.1 billion, or 2%, of Group operating income (excluding Corporate income and expense, net).

**OPPORTUNITY AND RISK SUMMARY**

We believe that our strategy, which is anchored in our company's tradition of leadership in innovation, positions us well to take advantage of trends shaping the future of the industry. These trends range from advances in science and technology that are opening new frontiers for research and development (R&D), to the growing and graying of populations that are boosting demand for chronic disease treatments.

At the same time, these trends contribute to certain risks and uncertainties in our operations. Some of them are inherent to the industry, and others are specific to Novartis. Anticipating and managing these risks can influence our ability to deliver strong financial performance and meet the needs of patients, healthcare providers, payors, regulators and shareholders.

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

**RESULTS OF OPERATIONS**

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

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, excluding 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, 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. For a reconciliation between IFRS results and core results see "Non-IFRS Measures as Defined by Novartis core results," below.

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

The core results, constant currencies and other non-IFRS measures are explained in more detail see "Non-IFRS Measures as Defined by Novartis", and are not intended to be substitutes for the equivalent measures of financial performance prepared in accordance with IFRS. These measures may differ from similarly titled non-IFRS measures of other companies.

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**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.

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,

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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 30. Discontinued Operations" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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.

**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.

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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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**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.

*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.

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*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).

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 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

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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 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

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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).

*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.

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*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 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

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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 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* ($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.

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***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).

| | 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.

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

| | 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) |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Operating income from continuing operations** | **8,268** | **17.0** | **8,977** | **18.2** | **(8)** | **(3)** |

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.

**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.

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**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.

**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

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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.

***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)** |
| Income from associated companies | 1,134 | 981 | 16 | 16 |
| Interest expense | (707) | (655) | (8) | (10) |
| Other financial income and expense | (99) | (24) | nm | nm |
| **Core income before taxes from continuing operations** | **13,315** | **14,092** | **(6)** | **(2)** |
| 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

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***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.

***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 30. Discontinued Operations" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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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.

**2015 Compared to 2014**

**Group overview**

On January 27, 2016, Novartis announced plans to further focus our divisions, integrating businesses that share therapeutic areas to better leverage our development and marketing capabilities. These plans included the transfer of the Ophthalmic Pharmaceuticals franchise from the Alcon Division to the Innovative Medicines Division (formerly named the Pharmaceuticals Division), and the transfer of selected mature products from the Innovative Medicines Division to the Sandoz Division. Operationally, these transfers were completed as of April 1, 2016. The centralization of manufacturing and the integration of some drug development functions, also announced on January 27, 2016, were operationally completed as of July 1, 2016.

In compliance with International Financial Reporting Standards (IFRS), Novartis updated its 2015 and 2014 segment financials to reflect these transfers, to aid comparability of year-on year results. As a result, all comparisons of divisional results from 2015 to 2014 reflect the new divisional structure.

In 2015, Novartis completed a series of portfolio transformation transactions, including the acquisition of oncology assets from GlaxoSmithKline plc (GSK) and a 36.5% interest in GSK Consumer Healthcare Holdings Ltd., and the divestment of its Vaccines and Animal Health businesses. To reflect these transactions, Novartis reported the Group's financial results in for all years presented as "continuing operations" and "discontinued operations." In addition, on January 9, 2014, Novartis completed the divestment to Grifols S.A. of our former blood transfusion diagnostics unit, which had been included in our former Vaccines and Diagnostics Division. The divestment gain and results of this divested business were also accounted for as discontinued operations and not included in our results from continuing operations. All comparisons from 2015 to 2014 are versus continuing operations, unless otherwise noted. See " Factors Affecting Comparability Of Year-On-Year Results Of Operations".

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**Key figures**

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

nm = not meaningful

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

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

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

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

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

Net income from discontinued operations amounted to $10.8 billion in 2015, which included $12.7 billion of pre-tax divestment gains and the operational results of the divested businesses until the respective dates of completion of the transactions, compared to a net loss of $447 million in 2014. For more information on discontinued operations see " Factors Affecting Comparability of Year-On-Year Results of Operations", below and "Note 30. Discontinued Operations" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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

**Growth**

Across our divisions, our portfolio of growth products continued to support performance in 2015. Sales of growth products increased 17% to $16.6 billion, or 34% of net sales, demonstrating our ability to renew our product portfolio and helping offset the impact of patent expirations. In our Innovative Medicines Division, sales of growth products increased 31% (cc) and accounted for 43% of net sales, up from 35% in 2014.

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

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

Although overall Alcon performance lagged in 2015, some products continued to do well. Alcon saw continued growth in sales of its innovative *Dailies Total1* contact lenses and of disposable cataract and vitreoretinal surgical supplies.

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

**Productivity**

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

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

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

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

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***Net Sales by Segment***

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

| | Year ended Dec 31, 2015 | Year ended Dec 31, 2014 | Change in $ | Change in constant currencies |
|---|---|---|---|---|
| | $ m | $ m | % | % |
| Innovative Medicines[1],[2] | 33,345 | 34,828 | (4) | 6 |
| Sandoz[2] | 10,070 | 10,736 | (6) | 5 |
| Alcon[2] | 5,999 | 6,616 | (9) | (1) |
| **Net sales to third parties from continuing operations** | **49,414** | **52,180** | **(5)** | **5** |

(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 delivered net sales of $33.3 billion ( 4%, +6% in constant currencies, or cc) as increased volumes, including from the oncology portfolio acquired from GlaxoSmithKline (GSK) in 2015, countered the impact of greater generic competition, which reduced sales by 6 percentage points.

Growth products generated $14.4 billion of division net sales, growing 31% (cc) compared to last year. These products which include *Gilenya*, *Tasigna*, *Ultibro*, the combination of *Tafinlar + Mekinist*, *Jakavi, Revolade* and *Cosentyx* contributed 43% of division net sales, compared to 35% in 2014.

Sales in emerging growth markets increased 8% (cc) to $8.4 billion.

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

*Oncology*

Oncology sales rose 14% (+23% cc) to $13.3 billion, boosted by the newly acquired portfolio from GSK and continued growth in our existing products. By brand, growth drivers included *Afinitor*, up 10% (cc) to $1.6 billion; *Tasigna*, up 16% (cc) to $1.6 billion; and *Jakavi*, up 71% (cc) to $410 million.

*Ophthalmology*

Sales in Ophthalmology were $5.9 billion ( 12%, 2% cc), driven mainly by lower sales of *Lucentis*, which faced increased competitive pressure in Japan and some European markets.

*Neuroscience*

Neuroscience sales were $3.6 billion ( 2%, +6% cc), with *Gilenya* rising 12% (+21% cc) to $2.8 billion and more than offsetting declines in *Exelon/Exelon* Patch due to generic competition.

*Immunology and Dermatology*

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

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*Respiratory*

Respiratory sales were $1.4 billion (+5%, +23% cc). We had sales of $576 million (+19%, +40% cc) for our portfolio of drugs for chronic obstructive pulmonary disease (COPD), including *Onbrez Breezhaler/Arcapta Neohaler*, *Seebri Breezhaler* and *Ultibro Breezhaler.* Sales of *Xolair* reached $755 million ( 3%, +14% cc), including as a treatment for chronic hives.

*Cardio-Metabolic*

Cardio-Metabolic sales were $1.2 billion ( 6%, +9% cc)*Entresto* was launched in the US in the third quarter and full-year sales reached $21 million. *Galvus* sales were $1.1 billion ( 7%, +8% cc).

*Established Medicines*

Established Medicines sales were $5.8 billion ( 28%, 19% cc). Established medicines such as *Diovan* ($1.3 billion, 40% cc) and *Exforge* ($1.0 billion, 15% cc) continued to see declines as a result of generic competition.

**TOP 20 INNOVATIVE MEDICINES[1] PRODUCT NET SALES 2015**

| | | | US | | Rest of world | | Total | | |
|---|---|---|---|---|---|---|---|---|---|
| **Brands** | **Business Franchise** | **Indication** | **$ m** | **% change in constant currencies** | **$ m** | **% change in constant currencies** | **$ m** | **% change in $** | **% change in constant currencies** |
| ***Gleevec/Glivec*** | Oncology | Chronic myeloid leukemia and GIST | 2,533 | 17 | 2,125 | (5) | **4,658** | **(2)** | **5** |
| ***Gilenya*** | Neuroscience | Relapsing multiple sclerosis | 1,497 | 26 | 1,279 | 17 | **2,776** | **12** | **21** |
| ***Lucentis*** | Ophthalmology | Age-related macular degeneration | | | 2,060 | (2) | **2,060** | **(16)** | **(2)** |
| ***Tasigna*** | Oncology | Chronic myeloid leukemia | 661 | 22 | 971 | 12 | **1,632** | **7** | **16** |
| ***Sandostatin*** | Oncology | Carcinoid tumors and Acromegaly | 823 | 10 | 807 | 5 | **1,630** | **(1)** | **7** |
| ***Afinitor/Votubia*** | Oncology | Breast cancer / TSC | 892 | 11 | 715 | 9 | **1,607** | **2** | **10** |
| ***Diovan/Co-Diovan*** | Established Medicines | Hypertension | 254 | (74) | 1,030 | (17) | **1,284** | **(45)** | **(40)** |
| ***Galvus*** | Cardio-Metabolic | Diabetes | | | 1,140 | 8 | **1,140** | **(7)** | **8** |
| ***Exforge*** | Established Medicines | Hypertension | 67 | (76) | 980 | 1 | **1,047** | **(25)** | **(15)** |
| ***Exjade*** | Oncology | Chronic iron overload | 365 | 19 | 552 | 3 | **917** | **(1)** | **8** |
| ***Xolair[2]*** | Respiratory | Asthma | | | 755 | 14 | **755** | **(3)** | **14** |
| ***Exelon/Exelon* Patch** | Neuroscience | Alzheimer's disease | 340 | (30) | 388 | (13) | **728** | **(28)** | **(21)** |
| **Travoprost Group** | Ophthalmology | Reduction of elevated intraocular pressure | 199 | (8) | 432 | (2) | **631** | **(14)** | **(4)** |
| ***Neoral/Sandimmun(e)*** | Immunology and Dermatology | Transplantation | 47 | (15) | 523 | (5) | **570** | **(17)** | **(6)** |
| ***Votrient*** | Oncology | Renal cell carcinoma | 287 | nm | 278 | nm | **565** | **nm** | **nm** |
| ***Voltaren (excl. other divisions)*** | Established Medicines | Inflammation/pain | | | 558 | 0 | **558** | **(12)** | **0** |
| **Topical Olopatadine Group** | Ophthalmology | Allergic Conjunctivitis | 317 | (10) | 140 | (2) | **457** | **(11)** | **(8)** |
| ***Tafinlar/Mekinist*** | Oncology | Melanoma | 267 | nm | 186 | nm | **453** | **nm** | **nm** |
| ***Myfortic*** | | Transplantation | 109 | (27) | 332 | 0 | **441** | **(19)** | **(8)** |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Immunology and Dermatology | | | | | | | | |
| **Jakavi** | Oncology | Myelofibrosis | | | 410 | 71 | **410** | **47** | **71** |
| **Top 20 products total** | | | **8,658** | **5** | **15,661** | **5** | **24,319** | **(5)** | **5** |
| Rest of portfolio | | | 3,192 | 6 | 5,834 | 8 | **9,026** | **(3)** | **7** |
| **Total Division sales** | | | **11,850** | **5** | **21,495** | **6** | **33,345** | **(4)** | **6** |

(1) Formerly named the Pharmaceutical Division.

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

nm = not meaningful

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*Gleevec/Glivec* ($4.7 billion, +5% cc) is a treatment for adult patients with metastatic and/or unresectable KIT+ gastrointestinal stromal tumors (GIST), as an adjuvant treatment for certain adult patients following resection of KIT+ GIST, and as a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). Sales growth were driven mainly by the US, and more than compensated for the loss of patent exclusivity in some markets. In the US, Novartis Pharmaceuticals Corporation has settled its litigation with a subsidiary of Sun Pharmaceutical Industries Ltd. relating to Novartis patents covering the use of certain polymorphic forms of *Gleevec/Glivec*, which expire in 2019 (including pediatric exclusivity). The basic compound patent for *Gleevec/Glivec* expired in the US on July 4, 2015. As a result of the settlement, Novartis will permit Sun's subsidiary to market a generic version of *Gleevec/Glivec* in the US commencing on February 1, 2016.

*Gilenya* ($2.8 billion, +21% cc), the first once-daily oral therapy to treat relapsing forms of multiple sclerosis (RMS), continued to outgrow the market, achieving double-digit growth in 2015 in recognition of strong trends towards oral treatments with higher efficacy. Growth was also fueled by an increasing acceptance of the role of high-efficacy treatments when used earlier in the course of the disease. *Gilenya* continues to see volume growth through new patient initiations in both the US and non-US markets. In the US, *Gilenya* is indicated for relapsing forms of MS. In the EU, *Gilenya* is indicated for adult patients with high disease activity despite treatment with at least one disease modifying agent, or rapidly evolving severe relapsing remitting MS. In an expanding oral market with multiple options, *Gilenya* is the only oral disease-modifying therapy (DMT) to impact the course of RMS with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. *Gilenya* has an overall positive benefit-risk profile with over ten years of safety experience. As of November 30, 2015, *Gilenya* has been used to treat approximately 134,000 patients in clinical trials and in a post-marketing setting, with a total patient exposure of approximately 289,000 patient years. *Gilenya* is currently approved in over 80 countries around the world. *Gilenya* is licensed from Mitsubishi Tanabe Pharma.

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

*Tasigna* ($1.6 billion, +16% cc) performance was driven by strong growth in the US and other markets. *Tasigna* is currently approved as a first-line therapy for newly diagnosed patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase in more than 85 countries globally, including the US, EU, Japan and Switzerland, with additional submissions pending worldwide. *Tasigna* (nilotinib) is also approved in more than 110 countries as a second-line treatment for patients with Ph+ CML in chronic and/or accelerated phase who are resistant or intolerant to existing treatment, such as *Gleevec/Glivec*.

*Sandostatin* ($1.6 billion, +7% cc) continued to benefit from the increasing use of *Sandostatin LAR* (long acting release) in key markets and from the launch of the enhanced presentation (now approved in 69 countries) which includes a diluent, safety needle and vial adapter. *Sandostatin* is a somatostatin analogue used to treat patients with acromegaly as well as neuroendocrine tumors (NET). In NET, it is used for both the treatment of patients with symptoms of carcinoid syndrome and those with advanced NET of the midgut or unknown primary tumor location (currently approved in more than 60 countries).

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*Afinitor/Votubia* ($1.6 billion, +10% cc) performance was driven by strong growth in the US, Japan and other markets. *Afinitor* is an oral inhibitor of the mTOR pathway approved in combination with exemestane for the treatment of patients with HR+/HER2 advanced breast cancer after failure with a non-steroidal aromatase inhibitor (NSAI), for advanced renal cell carcinoma (RCC) following vascular endothelial growth factor-targeted therapy (after failure of sunitinib and sorafenib in the US) and for the treatment of advanced pancreatic neuroendocrine tumors (NET). *Afinitor* is also approved for treatment of patients with subependymal giant cell astrocytoma (SEGA) and renal angiomyolipoma associated with tuberous sclerosis complex (TSC), including as a dispersible tablet formulation in the US and EU for SEGA. Everolimus is also in Phase III development for patients with nonfunctional gastrointestinal and lung NET, HER2+ breast cancer, diffuse large B-cell lymphoma and TSC-related seizures. Everolimus, the active ingredient in *Afinitor/Votubia*, is available under the trade names *Zortress/Certican* for use in other non-oncology indications and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

*Diovan* Group ($1.3 billion, 40% cc), consisting of *Diovan* monotherapy and the combination product *Co-Diovan/Diovan* HCT, continues to retain a blockbuster status despite generic competition in most markets, including the US (following July 7, 2014 *Diovan* monotherapy generic entry), many EU countries and Japan (generic entry in June 2014). Sales continued to grow in Emerging Growth Markets, including China and selected countries in Latin America, Asia Pacific and Africa, partially compensating for loss of exclusivity in the US and the EU.

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

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

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

*Xolair* ($755 million, +14% cc), a biologic drug for appropriate patients with severe persistent allergic asthma in Europe and moderate-to-severe persistent allergic asthma in the US, is currently approved in more than 90 countries. Its sales continued to grow strongly in Canada, Europe and Latin America. *Xolair* is also approved in the EU, Switzerland and over 40 other countries as a treatment for chronic spontaneous urticaria (CSU), also known as chronic idiopathic urticaria (CIU), for which it is approved in the US and now Canada and Australia. Novartis co-promotes *Xolair* with Genentech in the US and shares a portion of the operating income, but does not book US sales.

*Exelon/Exelon* Patch ($728 million, 21% cc) sales declined due to generic competition for *Exelon* Patch in the EU and now in the US. *Exelon* Patch is approved for the treatment of mild-to-moderate Alzheimer's disease dementia (AD) in more than 90 countries, including more than 20 countries where it is also approved for

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Parkinson's disease dementia. *Exelon* Patch is also indicated for the treatment of patients with severe AD in 14 countries, including the US.

Travoprost Group ($631 million, 4% cc), including *Travatan*, *Travatan Z* and *DuoTrav*, is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or who have ocular hypertension. Sales declined mainly due to increased generic competition for *Travatan Z*. Single agent travoprost products (*Travatan*, *TravatanZ*, *Travatan BAK-Free* and *Izba*) are prescribed as first-line agents and are marketed in more than 140 countries, including the US, EU countries, 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

*Neoral/Sandimmun* ($570 million, 6% cc), a micro-emulsion formulation of cyclosporine, is an immunosuppressant to prevent organ rejection following a kidney, liver or heart transplant. *Neoral* is also approved for use in lung transplant in many countries outside of the US. Additionally, it is indicated for treating selected autoimmune disorders such as psoriasis and rheumatoid arthritis. First launched in 1995, *Neoral* is marketed in approximately 100 countries. Although sales are declining due to generic competition and mandatory price reductions, most notably in Europe and Japan, the decrease is not as rapid as has been the case in other therapeutic areas, due to the special characteristics of the solid organ transplant market.

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

*Voltaren/Cataflam* ($558 million, 0% cc), is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions. *Voltaren/Cataflam* was first registered in 1973 and is available in more than 140 countries. This product, which is subject to generic competition, is marketed by the Innovative Medicines Division in a wide variety of dosage forms, including tablets, drops, suppositories, ampoules and topical therapy. In addition, in various countries, our Sandoz Division markets generic versions of the product and our Alcon Division markets *Voltaren* for ophthalmic indications.

Topical Olopatadine Group ($457 million, 8% cc) includes *Patanol*, *Pataday* and *Pazeo*, which are olopatadine hydrochloride ophthalmic solutions of different concentrations that are approved to treat the signs and symptoms of allergic conjunctivitis (*Patanol*), as well as ocular itching associated with allergic conjunctivitis (*Pataday* and *Pazeo*). The sales decline for the Topical Olopatadine Group was driven by lower sales for *Patanol* and *Pataday*. Olopatadine products are marketed in more than 100 countries, including the US, EU countries, Canada and China.

*Tafinlar + Mekinist* ($453 million) achieved strong growth in sales. Acquired from GSK in 2015, this combination is the first of its kind for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, as detected by a validated test, in the US, EU, Canada and several other markets. In August, the combination of *Tafinlar + Mekinist* was approved in Europe for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation and in November, this combination received regular approval in the US based on the completion of two Phase III confirmatory trials. The combination was previously approved in the US under accelerated approval. *Tafinlar* targets the serine/threonine kinase BRAF in the RAS/RAF/MEK/ERK pathway and *Mekinist* targets the threonine/tyrosine kinases MEK1 and MEK2 in the MAP kinase pathway, resulting in dual blockade of this pathway, improving the clinical efficacy of the treatment. This is the first combination of BRAF/MEK inhibitors to achieve a median overall survival of more than two years in two Phase III studies in BRAF V600 mutation positive unresectable or metastatic melanoma patients. *Tafinlar + Mekinist* are also approved as single agents for the treatment of patients with unresectable or

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metastatic melanoma in more than 45 and 30 countries worldwide, respectively. In addition, *Tafinlar* also has Breakthrough Therapy designation from the FDA for treatment of non-small cell lung cancer (NSCLC) patients with BRAF V600E mutations who have received at least one prior line of platinum-containing chemotherapy. In July, the combination therapy *Tafinlar + Mekinist* also received Breakthrough Therapy designation from the FDA for NSCLC patients with BRAF V600E mutations.

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

*Jakavi* ($410 million, +71% cc) performance was driven by strong volume growth across multiple markets. *Jakavi* is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. It is the first JAK inhibitor indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thromboycythemia myelofibrosis. *Jakavi* is currently approved in more than 95 countries, including EU member states, Japan and Canada. In March 2015, the EC approved *Jakavi* for the treatment of adult patients with polycythemia vera (PV) who are resistant to or intolerant of hydroxyurea. *Jakavi* is the first targeted treatment approved by the EC for these patients. More than 45 countries have approved *Jakavi* in the PV indication, including Switzerland, Canada and Japan, and regulatory applications have been submitted in other countries. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US.

**Sandoz**

In 2015, Sandoz had net sales of $10.1 billion ( 6%, +5% in constant currencies, or cc, from the prior year).

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

| | Year ended Dec 31, 2015[1] | Year ended Dec 31, 2014[1] | Change in $ | Constant currencies change |
|---|---|---|---|---|
| | $ m | $ m | % | % |
| Retail Generics | 8,718 | 9,583 | (9) | 2 |
| Biopharmaceuticals | 772 | 618 | 25 | 39 |
| Anti-Infectives (Partner label/API) | 580 | 535 | 8 | 18 |
| **Total** | **10,070** | **10,736** | **(6)** | **5** |

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

*Retail Generics*

In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals. The Retail Generics franchise includes products in the therapeutic areas of dermatology, respiratory, oncology, transplantation and ophthalmics, as well as finished dosage forms of anti-infective products sold under the Sandoz name. Retail *Generics* sales worldwide were $8.7 billion ( 9%, +2% cc). New product launches included US-authorized generics of our Innovative Medicines Division's *Exelon Patch* and *Exforge*, as well as bivalirudin, an injectable anticoagulant.

*Biopharmaceuticals*

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- and biotechnology-based products known as biosimilars, as well as *Glatopa*. Sandoz also provides biotechnology manufacturing services to other companies. Sales of biopharmaceuticals rose 25% (+39% cc) to $772 million. Sandoz further strengthened

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its leadership in biosimilars in 2015 with the US approval of *Zarxio* (filgrastim), used to fight infection in cancer patients receiving chemotherapy.

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

*Anti-Infectives*

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

**Alcon**

Alcon net sales in 2015 were $6.0 billion ( 9%, 1% in constant currencies, or cc). Regionally, sales decreased in Japan and rose in Latin America and the Caribbean. In Europe, the Middle East and Africa, sales were flat (0% cc), with strong sales of recently launched contact lenses, including *Dailies Total1* and *Air Optix Colors*, offset by declines in surgical equipment.

Sales in North America declined 1%, mainly due to a slowdown in contact lens care and surgical equipment sales. In Asia and Russia, sales declined 8% (cc), driven by a significant market slowdown, with weak performance in China, India and Southeast Asia.

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

| | Year ended Dec 31, 2015[1] | Year ended Dec 31, 2014[1] | Change in $ | Constant currencies change |
|---|---|---|---|---|
| | $ m | $ m | % | % |
| **Surgical** | | | | |
| Cataract products | 2,853 | 3,174 | (10) | (2) |
| *of which IOLs* | *1,099* | *1,264* | *(13)* | *(4)* |
| Vitreoretinal products | 594 | 615 | (3) | 6 |
| Refractive/other | 251 | 284 | (12) | (5) |
| **Total** | **3,698** | **4,073** | **(9)** | **(1)** |
| **Vision Care** | | | | |
| Contact lenses | 1,743 | 1,897 | (8) | 1 |
| Contact lens care | 558 | 646 | (14) | (8) |
| **Total** | **2,301** | **2,543** | **(10)** | **(2)** |
| **Total net sales** | **5,999** | **6,616** | **(9)** | **(1)** |

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

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*Surgical*

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

*Vision Care*

Vision Care sales were $2.3 billion ( 10%, 2% cc). Contact lens sales reached $1.7 billion ( 8%, +1% cc), with strong sales of innovative lenses, particularly *Dailies Total1* and *Air Optix Colors,* offset by declines in older products. Sales of contact lens solutions were $0.6 billion ( 14%, 8% cc), affected by ongoing market shifts to daily disposable lenses, as well as competitive pressure in the US.

**Operating Income from Continuing Operations**

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

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

| | Year ended Dec 31, 2015 | % of net sales | Year ended Dec 31, 2014 | % of net sales | Change in $ | Change in constant currencies |
|---|---|---|---|---|---|---|
| | $ m | | $ m | | % | % |
| **Innovative Medicines[1],[2]** | **7,815** | **23.4** | **8,826** | **25.3** | **(11)** | **6** |
| **Sandoz[2]** | **1,300** | **12.9** | **1,570** | **14.6** | **(17)** | **(7)** |
| **Alcon[2]** | **281** | **4.7** | **760** | **11.5** | **(63)** | **(33)** |
| Corporate | (419) | | (67) | | nm | nm |
| **Operating income from continuing operations** | **8,977** | **18.2** | **11,089** | **21.3** | **(19)** | **(2)** |

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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**Core Operating Income key figures[1]**

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

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

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

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

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

| | Year ended Dec 31, 2015 | % of net sales | Year ended Dec 31, 2014 | % of net sales | Change in $ | Change in constant currencies |
|---|---|---|---|---|---|---|
| | $ m | | $ m | | % | % |
| **Innovative Medicines[1],[2]** | **10,862** | **32.6** | **11,075** | **31.8** | **(2)** | **13** |
| **Sandoz[2]** | **2,045** | **20.3** | **2,101** | **19.6** | **(3)** | **9** |
| **Alcon[2]** | **1,235** | **20.6** | **1,720** | **26.0** | **(28)** | **(15)** |
| Corporate | (352) | | (423) | | 17 | 11 |
| **Core operating income from continuing operations** | **13,790** | **27.9** | **14,473** | **27.7** | **(5)** | **10** |

(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**

Operating income was $7.8 billion ( 11%, +6% cc) and included the effects of the acquisition of GSK's oncology portfolio, among other exceptional items.

Core operating income, which excludes certain exceptional items, was $10.9 billion ( 2%, +13% cc), helped by our ongoing efforts to improve productivity and control costs. Core operating income margin improved by 2.1 percentage points in constant currencies. However, that was offset by 1.3 percentage points of negative impact from currency exchange rates, yielding a core margin of 32.6% of net sales.

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*Research and development*

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

| | Year ended Dec 31, 2015[1] | Year ended Dec 31, 2014[1] | Change in $ | Change in constant currencies |
|---|---|---|---|---|
| | $ m | $ m | % | % |
| Research and Exploratory Development | (2,739) | (2,894) | 5 | 3 |
| Confirmatory Development | (4,946) | (4,893) | (1) | (6) |
| **Total Innovative Medicines Division Research and Development expense** | **(7,685)** | **(7,787)** | **1** | **(3)** |
| *as % of Innovative Medicines net sales to third parties* | *23.0* | *22.4* | | |
| Core Research and Exploratory Development | (2,663) | (2,812) | 5 | 3 |
| Core Confirmatory Development | (4,839) | (4,620) | (5) | (10) |
| **Total Core Innovative Medicines Division Research and Development expense** | **(7,502)** | **(7,432)** | **(1)** | **(5)** |
| *as % of Innovative Medicines net sales to third parties* | *22.5* | *21.3* | | |

(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 expenditure amounted to $2.7 billion in 2015, a decrease of 5% (+3% cc) compared to 2014. Confirmatory Development expenditures increased by 1% ( 6% cc) to $4.9 billion, mainly driven by additional development expense for the newly acquired Oncology assets. Core R&D expense in the Innovative Medicines Division as percent of sales was flat in constant currencies, and currency had a negative impact of 1.2 percentage points mainly from the sales base, as the Core R&D expenses are primarily denominated in US dollars and Swiss francs, which resulted in a net increase of 1.2 percentage points to 22.5% of net sales.

**Sandoz**

Operating income was $1.3 billion ( 17%, 7% cc).

Core operating income, which excludes certain exceptional items, decreased 3% (+9% cc) to $2.0 billion. Core operating income margin increased 0.8 percentage points in constant currencies and currency exchange rates had a negative impact of 0.1 percentage points, yielding a core margin of 20.3% of net sales.

**Alcon**

Operating income was $0.3 billion ( 63%, 33% cc).

Core operating income, which excludes certain items, was $1.2 billion ( 28%, 15% cc), impacted by lower sales, investments in product development, and increased provisions for bad debt in Asia. Core operating income margin declined 3.5 percentage points in constant currencies and currency exchange rates had a negative impact of 1.9 percentage points, yielding a core margin of 20.6% of net sales.

**Corporate Income and Expense, Net**

Corporate income and expense amounted to a net expense of $419 million in 2015 compared to a net expense of $67 million in the prior year. The increased expense was mainly due to the $302 million commercial settlement gain and a $248 million gain from selling Novartis Venture Fund investments recorded in 2014,

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partially offset by the gain on the sale of real estate in Switzerland of $54 million, lower share-based compensation accruals and lower provisions in the captive insurance companies in 2015.

**Non-Operating Income and Expense**

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

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

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

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

| | | | | |
|---|---|---|---|---|
| Core basic EPS ($) from discontinued operations | (0.11) | 0.04 | nm | nm |
| **Core basic EPS ($)** | **4.90** | **5.23** | **(6)** | **7** |

nm = not meaningful

***Income from associated companies***

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

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

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

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

***Interest Expense and other financial income and expense***

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

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

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

***Taxes***

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

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

***Net Income***

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

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

***EPS***

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

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

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**Discontinued Operations**

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

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

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

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

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

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

Net income from discontinued operations amounted to $10.8 billion in 2015 compared to a net loss $447 million in 2014. For more information on discontinued operations see " Factors Affecting Comparability of Year-On-Year Results of Operations", below and "Note 30. Discontinued Operations" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**Total Group**

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

**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 2016 and 2015 are mentioned below.

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**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. Results of operations since the date of acquisition were not material.

*Innovative Medicines Acquisition of SELEXYS PHARMACEUTICALS CORPORATION*

On November 18, 2016, Novartis acquired Selexys Pharmaceuticals Corporation (Selexys), a privately-held, US-based company specializing in development of therapeutics in certain hematologic and inflammatory disorders, following receipt of results of the SUSTAIN study. The fair value of the total purchase consideration for acquiring the 81% stake Novartis did not already own amounted to $268 million. Results of operations since the date of acquisition were not material.

**Significant transactions in 2015**

**PORTFOLIO TRANSFORMATION TRANSACTION**

In 2015, Novartis completed a series of portfolio transformation transactions as follows:

**Transaction with Eli Lilly and Company**

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

**Transactions with GlaxoSmithKline plc**

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

*Innovative Medicines Acquisition of GSK oncology products*

Novartis acquired GSK's oncology products and certain related assets for an aggregate cash consideration of $16.0 billion. In 2015, from the date of acquisition the business generated net sales of $1.8 billion. Management estimates that sales for the entire year 2015 would have amounted to $2.1 billion had the oncology products been acquired at the beginning of the 2015 reporting period. The 2015 net results from operations on a reported basis since the acquisition date were not material, mainly due to amortization of intangible assets.

*Vaccines Divestment*

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

*Consumer Health Combination of Novartis OTC with GSK Consumer Healthcare*

Novartis and GSK agreed to create a combined consumer healthcare business through the combination of Novartis OTC and GSK Consumer Healthcare businesses. On March 2, 2015, a new entity, GlaxoSmithKline Consumer Healthcare Holdings Ltd. (GSK Consumer Healthcare) was formed via the contribution of business from both Novartis and GSK. Novartis has a 36.5% interest in the newly created entity. Based on estimates of fair value exchanged, an investment in associated company of $7.6 billion was recorded. The resulting pre-tax gain, net of transaction related costs, of $5.9 billion is recorded in operating income from discontinued operations. The

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investment is accounted for using the equity method of accounting using estimated results for the last quarter of the year.

*Additional GSK related costs*

The GSK transaction resulted in $0.6 billion of additional transaction-related costs that were expensed, thereof $0.3 billion paid in 2015.

**Transaction with CSL**

On October 26, 2014, Novartis entered into an agreement with CSL to sell its Vaccines influenza business to CSL for $275 million. The transaction with CSL was completed on July 31, 2015, resulting in a partial reversal of the impairment recorded in 2014 in the amount of $0.1 billion, which is included in operating income from discontinued operations.

**Other significant transactions in 2015**

*Innovative Medicines Acquisition of SPINIFEX PHARMACEUTICALS, INC.*

On June 29, 2015, the Innovative Medicines Division acquired Spinifex Pharmaceuticals, Inc. (Spinifex), a US and Australia based, privately held development stage company, focused on developing a peripheral approach to treat neuropathic pain. The transaction closed on July 24, 2015, and the fair value of the total purchase consideration was $312 million. The 2015 results of operations since the date of acquisition were not material.

*Innovative Medicines Acquisition of ADMUNE THERAPEUTICS LLC*

On October 16, 2015, the Innovative Medicines Division acquired Admune Therapeutics LLC (Admune), a US-based, privately held company, broadening the Novartis pipeline of cancer immunotherapies. The fair value of the total purchase consideration amounted to $258 million. The 2015 results of operations since the date of acquisition were not material.

For further details on significant transactions in 2016 and 2015, see "Note 2. Significant Transactions" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**Classification as continuing operations and discontinued operations**

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

Continuing operations comprise the businesses of the Innovative Medicines, Sandoz and Alcon Divisions as well as the continuing Corporate activities. Continuing operations also include the results from oncology assets acquired from GSK and the estimated results from the 36.5% interest in GSK Consumer Healthcare Holdings Ltd. for the period from March 2, 2015 (the latter reported as part of income from associated companies).

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

Discontinued operations in 2015 also included the exceptional pre-tax gain of $12.7 billion from the divestment of Animal Health ($4.6 billion) and from the transactions with GSK ($2.8 billion from the Vaccines non-influenza business and $5.9 billion arising from the contribution of Novartis OTC into GSK Consumer Healthcare Holdings Ltd.). In addition the GSK transactions resulted in $0.6 billion of additional transaction-related costs, which were expensed and reported in Corporate discontinued operations.

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

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

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## 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 2016" furnished to the SEC on Form 6-K on January 25, 2017, 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.

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 sales of our products. 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.

*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

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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 for 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 2016, sales returns amounted to approximately 1% of gross product sales. If sufficient experience is not available, sales are only recorded based on evidence of product consumption or when the right of return has expired.

We enter into distribution service agreements with major wholesalers, which provide a financial disincentive for the wholesalers to purchase product quantities in excess of current customer demand. Where possible, we adjust shipping patterns for our products to maintain wholesalers' 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 | | Change in provisions offset against gross trade receivables | Revenue deductions provisions at December 31 |
|---|---|---|---|---|---|---|---|
| | | | | Adjustments of prior years | Current year | | |
| | $ m | $ m | $ m | $ m | $ m | $ m | $ m |
| **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** |
| **2014** | | | | | | | |
| US-specific healthcare plans and program rebates | 1,376 | | (3,118) | (186) | 3,025 | | 1,097 |
| Non-US-specific healthcare plans and program rebates | 1,145 | (124) | (1,743) | (19) | 1,787 | (31) | 1,015 |
| Non-healthcare plans and program-related rebates, returns and other deductions | 1,427 | (83) | (9,046) | (52) | 9,564 | (389) | 1,421 |
| **Total continuing operations 2014** | **3,948** | **(207)** | **(13,907)** | **(257)** | **14,376** | **(420)** | **3,533** |

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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 | |
| **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** |
| **2014[1]** | | | | |
| **Innovative Medicines gross sales subject to deductions** | | | **43,768** | **100.0** |
| US-specific healthcare plans and program rebates | (2,524) | | (2,524) | (5.8) |
| Non-US-specific healthcare plans and program rebates | (1,293) | (830) | (2,123) | (4.8) |
| Non-healthcare plans and program-related rebates, returns and other deductions | (2,395) | (1,898) | (4,293) | (9.8) |
| **Total Innovative Medicines gross to net sales adjustments** | **(6,212)** | **(2,728)** | **(8,940)** | **(20.4)** |
| **Innovative Medicines net sales 2014** | | | **34,828** | **79.6** |

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

**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

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

Due to the above factors and those further described in "Note 1. Significant Accounting Policies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, actual cash flows and values could vary significantly from forecasted future cash flows and related values derived using discounting techniques.

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 11. Goodwill and Intangible Assets" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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

In 2015, intangible asset impairment charges of continuing operations amounted to $206 million ($178 million in the Innovative Medicines Division and $27 million in the Sandoz Division and $1 million in the Alcon Division).

In 2016, there was no reversal of prior year impairment charges (2015: $40 million).

Goodwill and other intangible assets represent a significant part of our consolidated balance sheet, primarily due to acquisitions. Although no significant additional impairments are currently anticipated, impairment evaluation could lead to material impairment charges in the future. For more information, see "Note 11. Goodwill and Intangible Assets" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

Additionally, net impairment charges for property, plant and equipment from continuing operations during 2016 amounted to $102 million (2015: $80 million).

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**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 and other countries, and evaluates trade receivables in these countries for potential collection risks. Substantially all of the trade receivables overdue from such countries are due directly from local governments or from government-funded entities. Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time that it takes to collect these trade receivables and may require Novartis to re-evaluate the collectability of these trade receivables in future periods.

**Contingent Consideration**

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

**Impairment of Associated Companies Accounted for at Equity**

Novartis considers investments in associated companies for impairment evaluation whenever indicators are noted for example when there is a quoted share price indicating a fair value less than the per-share balance sheet carrying value for the investment.

"Marketable securities" are financial assets recorded in Corporate and consisting principally of quoted equity and quoted debt securities as well as fund investments which are principally traded in liquid markets. Marketable securities that are held for long-term strategic purposes and typically recorded in the Divisions are classified as non-current financial assets. They include equity securities and fund investments.

**Retirement and Other Post-Employment Benefit Plans**

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

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Assumptions and estimates used by the Group may differ materially from the actual results we experience due to changing market and economic conditions, higher or lower withdrawal rates, and longer or shorter life spans of participants among other factors. For example, in 2016, a decrease in the interest rate we apply in determining the present value of the defined benefit obligations of one quarter of one percent would have increased our year-end defined benefit pension obligation for plans in Switzerland, US, UK, Germany and Japan, which represent 95% of the Group total defined benefit pension obligation, by approximately $0.8 billion. Similarly, if the 2016 interest rate had been one quarter of one percentage point lower than actually assumed, net periodic pension cost for pension plans in these countries, which represent about 92% of the Group's total net periodic pension cost for pension plans, would have increased by approximately $27 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 25. Post-Employment Benefits for Associates" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**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 20. Provisions and other non-current Liabilities" and "Note 28 Commitments and Contigencies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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 US, the EU, Switzerland or Japan.

**Healthcare Contributions**

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

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

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

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

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

**Taxes**

We prepare and file our tax returns based on an interpretation of tax laws and regulations, and record estimates based on these judgments and interpretations. Our tax returns are subject to examination by the competent taxing authorities, which may result in an assessment being made requiring payments of additional tax, interest or penalties. 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 & 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.

**New Accounting Pronouncements**

See "Note 1. Significant Accounting Policies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**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, 2016.

**FACTORS AFFECTING RESULTS OF OPERATIONS**

**Transformational changes Fueling Demand**

*Golden age for medical research*

Innovation in medical science is accelerating, driven by new therapeutic approaches. The number of new treatments underscores this trend. For instance, the average annual number of new drug molecules approved by the US Food and Drug Administration from 2012 through 2016 increased 46% compared to the prior five years.

Researchers are developing exciting new ways to treat diseases. Examples include gene editing and gene therapies, as well as RNA-based treatments that can intervene in how cells create specific proteins. Oncology is a particularly fast-evolving field and includes advances such as cell therapies to attack cancer cells, and vaccines that help people ward off the development of cancer in the first place.

The sophisticated new treatment approaches emerging from this golden age of medical research offer society and patients new hope for tackling the many diseases that still lack effective treatments.

Digital technology is also playing an increasingly important role in healthcare. Remote monitoring of patients, advanced data analytics, and other digital applications are changing the way clinical trials are conducted, as well as the way patients are treated. Technology is also being used to augment the effectiveness of traditional medicines.

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This opens new possibilities for healthcare companies to further improve health outcomes for patients. It is also attracting technology companies to the healthcare industry. Their special skills make them potential partners for science-based companies like Novartis, which have skills they lack, such as deep clinical and regulatory expertise.

*Growing and graying populations*

The world's population continues to grow, with an additional 1 billion people expected to join the human race by 2030, bringing the total number of inhabitants to about 8.5 billion, predicts the United Nations. Most of this population growth is expected to be in the developing world, where there continues to be tremendous unmet medical need. The world's population also continues to age rapidly, with the number of people aged 60 or older expected to increase by more than 500 million by 2030, to 1.4 billion people.

At the same time, millions of people are migrating from rural areas to cities, sparking changes in lifestyle and diet that over time can affect their health. More than half the world's population now lives in cities and towns, and this number is expected to grow to about 5 billion people by 2030.

These trends are fueling a global increase in chronic diseases such as diabetes and heart disease that may require patients to follow years or even decades of treatment. Cancer and cardiovascular diseases will cause half of all deaths worldwide by 2025, predicts the World Health Organization.

*Rising pressure on healthcare costs*

These factors are contributing to higher demand for healthcare worldwide and putting healthcare systems under increasing cost pressure. Healthcare costs globally have risen at a rate of about 10% annually in recent years, according to Aon Hewitt, well above the general inflation rate. In many countries, overall spending on healthcare continues to grow as a proportion of total economic activity. The US spends the most, at 17% of all the goods and services produced in the country, according to the Organization for Economic Cooperation and Development.

Responding to the world's rising healthcare needs represents a significant opportunity for healthcare companies such as Novartis in the coming years and decades. However, healthcare companies also have an important role to play in ensuring healthcare systems are sustainable over the long haul.

The pressure on healthcare systems already has governments and health insurers looking for ways to slow the rise in spending, while still providing quality care for as many people as possible. In some cases, they are employing tough tactics, from limiting access to treatment and slowing the uptake of innovative new medicines, to shifting more of the cost to individual patients.

This trend means healthcare companies increasingly find themselves squeezed by conflicting demands to provide cost-effective treatments, while at the same time continuing to use the latest technology to pursue breakthrough medicines and devices. Rising costs have also helped fuel a heated public debate about the pharmaceutical industry's pricing practices and have prompted a heightened level of scrutiny.

Indeed, the possibility of political or regulatory action on drug prices has become a greater risk for the entire industry, including Novartis. Such action could take a variety of forms, from restrictions on price increases and mandates to provide broad access to treatments, to changes in intellectual property laws. For more on the risks Novartis faces and the steps we are taking to address them, please see " Approach to Risk Management" below. One response to rising costs that is gaining momentum with governments, insurers and healthcare companies is to shift healthcare systems toward a focus on producing better health outcomes, rather than simply paying for pills and healthcare services.

For instance, the European Commission has sanctioned a value-based tendering approach for medical devices that allows companies to include measures of health outcomes in their price calculations. Elsewhere, the US Centers for Medicare & Medicaid Services is a year ahead of schedule in reaching its target of converting 50% of spending to quality-based payments that take into account both health outcomes and cost-effectiveness.

Novartis has also advocated a value-based approach as a way of improving efficiency in healthcare, and has agreed to be reimbursed for certain products based partly on health outcomes.

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Taken together, the evolving trends we see in society and the healthcare industry reinforce our conviction that our strategy of focusing on innovation and improved health outcomes for patients is the correct one to steer us through a shifting healthcare landscape. Our attention remains on executing our strategy as effectively as possible.

**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 and Alcon Divisions, as well as certain products of our Sandoz Division, 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 2016, the impact of generic competition on our net sales amounted to $2.4 billion.

Some of our best-selling products have started to, 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 US, Japan and certain EU countries for most of 2016. In the remaining EU countries, certain of our *Glivec* intellectual property rights expired in December 2016, and generic competition there has begun. Looking forward, certain intellectual property protecting *Afinitor* and *Gilenya* will expire in 2018, 2019 and 2020. In addition, some of the patents protecting these products are being challenged in the US, raising the possibility of an earlier entry of generic competition.

To counter the impact of patent expirations, we continuously invest in R&D to rejuvenate our portfolio. For example, in 2016, we invested 18.6% of total net sales in R&D. One measure of the output of our efforts is the performance of our growth products products launched in a key market (EU, US, Japan) in 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). These products accounted for 35% of total net sales in 2016, up 20% ($) from the previous year.

*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 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, for the inclusion of more patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has become even more challenging.

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 US 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 is taking steps to accelerate innovation. It has started to see the results

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of its efforts, with the approval and launch in 2016 of two new intraocular lenses, *PanOptix* and *UltraSert*, as well as 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 growth products*

Our ability to grow depends not only on our pipeline delivery, but also on our commercial success, particularly with respect to our growth products, 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, or loss of intellectual property protection. In addition, our revenue could be significantly impacted by the timing and rate of commercial acceptance of key 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 our Oncology business, for example, *Afinitor* saw sales decline in 2016 due to new treatment options in advanced breast cancer and renal cell carcinoma in the US. Sales increases for *Afinitor* in other indications, such as neuroendocrine tumors of gastrointestinal or lung origin, were unable to compensate.

Our Alcon Division also faced significant competitive pressure in 2016. Alcon is implementing a growth plan to counteract this pressure, including steps such as accelerating innovation and increasing investments in new product launches. While we are starting to see signs of progress, such as contact lens market share gains in certain European countries where we started investing in direct-to-consumer advertising, there is no certainty that our actions and investments will be sufficient to offset competition and return the division to growth. Should our efforts fail to accomplish their goals, or fail to do so in a timely manner, it could have a material adverse impact on our business, financial condition, or results of operations beyond the near term, as well.

*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, particularly in the US, 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 on our ability to establish satisfactory rates of reimbursement for our products by governments, insurers and other payors.

We expect scrutiny to continue in 2017 and 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 US 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

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beyond legal requirements, we strive to meet evolving public expectations for ethical behavior. We have a significant global compliance program in place, and devote substantial time and resources to ensure that our business is conducted in a legal and publicly acceptable manner. Despite our efforts, any failure to comply with the law could lead to substantial liabilities that may not be covered by insurance and could affect our business and reputation.

Governments and regulatory authorities worldwide are also increasingly challenging practices previously considered to be legal and 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 2016 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 US and other countries, potentially large damage payments and agreements intended to regulate company behavior. This is why we continued to strengthen the Integrity & Compliance (I&C) function in 2016. The function now has 375 employees, 175 of whom were added in the last three years.

We also introduced a new Chief Ethics and Compliance Officer, reporting directly to the CEO, in 2016. The new Chief Ethics and Compliance Officer is also Head of Litigation, reporting to the Group General Counsel of Novartis. By bringing the I&C and Legal functions closer together, we can evaluate facts that are 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.

*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 introduce a greater chance for disruptions and liabilities. For example, government authorities monitor our manufacturing facilities, and if they fail to meet requirements, there is a risk that they could be shut down. Disturbances in our supply chain could lead to product shortages, lost revenue and litigation.

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 2016 were consistent with the year before. Out of a total of 206 inspections, all but four (98%) were without major findings. Novartis took a further step in 2016 in our ongoing commitment to improvement, realigning our quality organization into a single, enterprise-wide group under one leader.

*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 may

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experience periods of high inflation. This could lead them to devalue their currencies or set exchange controls, as Venezuela has done. Ongoing conditions in Venezuela and other such countries could lead to further devaluations, which could result in significant additional financial losses to the Group in the future.

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. As a result, we may incur significant impairment charges if the fair value of intangible assets and 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 for impairment. In 2016, for example, we recorded intangible asset impairment charges of $591 million. Impairment testing may lead to additional 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 laws in the jurisdictions in which we operate. However, the integrated nature of our worldwide operations can produce conflicting claims from revenue authorities as to the determination of profits to be taxed in individual countries. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the incidence of double taxation on our revenues and capital gains.

But in recent years, tax authorities around the world have increased their scrutiny of companies 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 the Anti Tax Avoidance Directive and continues to expand the application of the fiscal state aid policy and the respective investigation on tax ruling practices. These tax reform initiatives on the OECD and European levels also need local country implementation, including in our home country of Switzerland, which may result in significant changes to established tax principles and could lead to an increased risk of international tax disputes.

Although we have taken steps to be in compliance with the evolving OECD and European tax initiatives, and will continue to do so, significant uncertainties remain as to the outcome of the Swiss and other countries' tax reform efforts. Such 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, could require us to adapt our tax structure, increase our effective tax rate and adversely affect our financial results.

*IT security, data integrity & data privacy*

Our business is 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 breaches, breakdowns, malicious intrusions, 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 the protection of our data and information technology, like many companies, we have experienced such events and expect to continue to experience them in the future. We believe that the data security breaches we have experienced to date have not resulted in significant disruptions to our operations, and will not have a significant adverse effect on our current or future results of operations. However, we may not be able to prevent breakdowns or breaches in our systems that could have a material adverse effect on our business, financial condition, results of operation, or reputation.

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In addition, our use of information technologies, including the Internet, social media, mobile technologies, and technology-based medical devices as well as other routine business operations sometimes involves gathering personal information (including sensitive personal information) regarding our patients, vendors, customers, employees, collaborators and others. Breaches of our systems or other failures to protect such information could expose the personal information of third parties to unauthorized persons. Such information breaches could result in significant potential liability and reputational harm.

**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 with risk management, the risk portfolio and the related actions implemented by management. The Risk Committee informs the Board of Directors on a periodic basis.

The Group Risk Office coordinates and aligns the risk management processes, and reports to the Risk Committee on a regular basis on risk assessment and risk management. Organizational and process measures have been designed to identify and mitigate risks at an early stage. Organizationally, the responsibility for risk assessment and management is allocated to the divisions, 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 and Compliance and the Business Practices Office, providing support and controlling the effectiveness of the risk management in these respective areas.

Financial risk management is described in more detail in "Note 29. Financial Instruments Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**NON-IFRS MEASURES AS DEFINED BY NOVARTIS**

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

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

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

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

**Core Results**

The Group's core results including core operating income, core net income and core earnings per share exclude fully the amortization and impairment charges of intangible assets, excluding 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, 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 because, as 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.

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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/impairment 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.

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 $; and

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

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

We use these constant currency measures in evaluating the Group's performance, as 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**

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, and intangible, other non-current and financial assets, excluding marketable securities. Cash flows in connection with the acquisition or divestment of subsidiaries, associated companies and non-controlling interests in subsidiaries are not taken into account to determine free cash flow.

Free cash flow is presented as additional information because Novartis considers it to be a useful indicator of the Group's ability to operate without reliance on additional borrowing or use of existing cash. Free cash flow is a measure of the net cash generated that is available for debt repayment, investment in strategic opportunities and for returning to shareholders. Free cash flow is not intended to be a substitute measure for cash flow from operating activities as determined under IFRS.

**Net Debt**

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

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**Novartis Cash Value Added**

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

**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).

| | 2016 | 2015 | Change |
|---|---|---|---|
| | $ m | $ m | $ m |
| **Operating income from continuing operations** | **8,268** | **8,977** | **(709)** |
| Depreciation of property, plant & equipment | 1,489 | 1,470 | 19 |
| Amortization of intangible assets | 3,861 | 3,755 | 106 |
| Impairments of property, plant & equipment, and intangible assets | 693 | 246 | 447 |
| **EBITDA from continuing operations** | **14,311** | **14,448** | **(137)** |

***Enterprise value***

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

| | Dec 31, 2016 | Dec 31, 2015 | Change |
|---|---|---|---|
| | $ m | $ m | $ m |
| Market capitalization | 172,048 | 208,321 | (36,273) |
| Non-controlling interests | 59 | 76 | (17) |
| Financial debts and derivatives | 23,802 | 21,931 | 1,871 |
| Liquidity | (7,777) | (5,447) | (2,330) |
| **Enterprise value** | **188,132** | **224,881** | **(36,749)** |
| **Enterprise value/EBITDA** | **13** | **16** | |

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**2016 AND 2015 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS**

| | Innovative Medicines[1] | | Sandoz | | Alcon | | Corporate | | Total Group | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2016 | 2015[2] restated | 2016 | 2015[2] restated | 2016 | 2015[2] restated | 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 related items | | | | | | | | | | |
| Income | (68) | (22) | | (1) | | | (229) | (260) | (297) | (283) |
| Expense | 41 | 214 | | 1 | | | 223 | 250 | 264 | 465 |
| **Total acquisition or divestment 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) | | | | | | | | | (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 | 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 and 2014 Reconciliation of IFRS Results to Core Results 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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**2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS**

| | Innovative Medicines[1] | | Sandoz | | Alcon | | Corporate | | Total Group | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 2015[2] restated | 2014[2] restated | 2015[2] restated | 2014[2] restated | 2015[2] restated | 2014[2] restated | 2015 | 2014 | 2015 | 2014 |
| | $ m | $ m | $ m | $ m | $ m | $ m | $ m | $ m | $ m | $ m |
| IFRS operating income from continuing operations | **7,815** | **8,826** | **1,300** | **1,570** | **281** | **760** | **(419)** | **(67)** | **8,977** | **11,089** |
| **Amortization of intangible assets** | **2,367** | **1,401** | **447** | **448** | **895** | **891** | | **3** | **3,709** | **2,743** |
| Impairments | | | | | | | | | | |
| Intangible assets | 138 | 238 | 27 | 39 | 1 | | | | 166 | 277 |
| Property, plant & equipment related to the Group-wide rationalization of manufacturing sites | 6 | 23 | 83 | | | | | | 89 | 23 |
| Other property, plant & equipment | (45) | (8) | 14 | 7 | 1 | (1) | 21 | 23 | (9) | 21 |
| Financial assets | 32 | 20 | | 1 | | | 91 | 91 | 123 | 112 |
| **Total impairment charges** | **131** | **273** | **124** | **47** | **2** | **(1)** | **112** | **114** | **369** | **433** |
| Acquisition or divestment related items | | | | | | | | | | |
| Income | (22) | | (1) | | | | (260) | | (283) | |
| Expense | 214 | 33 | 1 | | | | 250 | | 465 | 33 |
| **Total acquisition or divestment related items, net** | **192** | **33** | **0** | | | | **(10)** | | **182** | **33** |
| Other items | | | | | | | | | | |
| Divestment gains | (626) | (237) | | | | | (54) | (294) | (680) | (531) |
| Restructuring items | | | | | | | | | | |
| Income | (30) | (59) | | (3) | (4) | (21) | (5) | | (39) | (83) |
| Expense | 422 | 664 | 121 | 21 | 29 | 63 | 57 | 1 | 629 | 749 |
| Legal-related items | | | | | | | | | | |
| Income | | | | | | | | | | |
| Expense | 578 | 125 | 40 | | 4 | | (30) | 30 | 592 | 155 |
| Additional income | (119) | (158) | (2) | | (5) | (29) | (68) | (315) | (194) | (502) |
| Additional expense | 132 | 207 | 15 | 18 | 33 | 57 | 65 | 105 | 245 | 387 |
| **Total other items** | **357** | **542** | **174** | **36** | **57** | **70** | **(35)** | **(473)** | **553** | **175** |
| **Total adjustments** | **3,047** | **2,249** | **745** | **531** | **954** | **960** | **67** | **(356)** | **4,813** | **3,384** |
| **Core operating income from continuing operations** | **10,862** | **11,075** | **2,045** | **2,101** | **1,235** | **1,720** | **(352)** | **(423)** | **13,790** | **14,473** |
| *As % of net sales* | **32.6%** | **31.8%** | **20.3%** | **19.6%** | **20.6%** | **26.0%** | | | **27.9%** | **27.7%** |
| Income from associated companies | | 812 | 2 | 4 | | | 264 | 1,102 | 266 | 1,918 |
| Core adjustments to income from associated companies, net of tax | | (812) | | | | | 715 | (163) | 715 | (975) |
| Interest expense | | | | | | | | | (655) | (704) |
| Other financial income and expense[3] | | | | | | | | | (24) | (31) |
| Taxes (adjusted for above items) | | | | | | | | | (2,051) | (2,028) |
| **Core net income from continuing operations** | | | | | | | | | **12,041** | **12,653** |

| | | |
|---|---|---|
| Core net income from discontinued operations[4] | (256) | 102 |
| **Core net income** | **11,785** | **12,755** |
| Core net income attributable to shareholders | 11,774 | 12,685 |
| **Core basic EPS from continuing operations ($)[5]** | **5.01** | **5.19** |
| Core basic EPS from discontinued operations ($)[5] | (0.11) | 0.04 |
| **Total core basic EPS ($)[5]** | **4.90** | **5.23** |

(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 in 2015 for charges of $0.4 billion related mainly to Venezuela subsidiaries.

(4) For details on discontinued operations reconciliation from IFRS to core net income, please refer to " 2015 and 2014 Reconciliation of IFRS Results to Core Results 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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**2016, 2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS GROUP**

| 2016 | IFRS results | Amortization of intangible assets[1] | Impairments[2] | Acquisition or divestment related items, including restructuring and integration charges[3] | Other items[4] | Core results |
|---|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Gross profit from continuing operations** | **31,916** | **3,758** | **96** | | **36** | **35,806** |
| **Operating income from continuing operations** | **8,268** | **3,801** | **786** | **(33)** | **165** | **12,987** |
| **Income before taxes from continuing operations** | **7,817** | **4,097** | **786** | **(33)** | **648** | **13,315** |
| Taxes from continuing operations[5] | (1,119) | | | | | (2,001) |
| **Net income from continuing operations** | **6,698** | | | | | **11,314** |
| **Net income** | **6,698** | | | | | **11,314** |
| **Basic EPS from continuing operations ($)[6]** | **2.82** | | | | | **4.75** |
| **Total basic EPS ($)[6]** | **2.82** | | | | | **4.75** |
| **The following are adjustments to arrive at Core Gross Profit from continuing operations** | | | | | | |
| Other revenues | 918 | | | | (50) | 868 |
| Cost of goods sold | (17,520) | 3,758 | 96 | | 86 | (13,580) |
| **The following are adjustments to arrive at Core Operating Income from continuing operations** | | | | | | |
| Marketing & Sales | (11,998) | | | | 7 | (11,991) |
| Research & Development | (9,039) | 43 | 495 | | 99 | (8,402) |
| General & Administration | (2,194) | | | | 74 | (2,120) |
| Other income | 1,927 | | (10) | (297) | (867) | 753 |
| Other expense | (2,344) | | 205 | 264 | 816 | (1,059) |
| **The following are adjustments to arrive at Core Income before taxes from continuing operations** | | | | | | |
| Income from associated companies | 703 | 296 | | | 135 | 1,134 |
| Other financial income and expense | (447) | | | | 348 | (99) |

(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 $296 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; Other income includes impairment reversals of property, plant and equipment; Other expense includes impairment charges related to property, plant and equipment, and financial assets.

(3)

Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include transitional service-fee income and expenses and other items related to the portfolio transformation; Other income also includes a gain from the revaluation of a previously held financial investment in a newly acquired company.

(4)

Other items: Other revenues include an early release of deferred income associated with a collaboration agreement; Cost of goods sold, Other income and Other expense include net restructuring and other charges related to the Group-wide rationalization of manufacturing sites; Research & Development, Marketing & Sales, Other income and Other expense include other restructuring income and charges; Cost of goods sold and Research & Development include adjustments of contingent considerations; General & Administration, Other income and Other expense include items related to setup costs for Novartis Business Services; Other income and Other expense also include legal settlements and changes in provisions; Other income also includes gains from product divestments, other income related to the portfolio transformation and a gain related to the sale of real estate; Other expense also includes a charge as a result of a pension plan amendment, a charge for an indirect tax settlement and other costs; Income from associated companies includes $135 million for the Novartis share of the estimated GSK Consumer Healthcare Holdings Ltd. core items; Other financial income and expense relates mainly to devaluation losses in Venezuela.

(5)

Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on other items, although this is not always the case for items arising from legal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments for continuing operations of $5.5 billion to arrive at the core results before tax amounts to $882 million. The average tax rate on the adjustments for continuing operations is 16.0% since the estimated full-year tax charge has been applied to the pre-tax income of the period.

(6)

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

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

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

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

(3)

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

(4)

Other items: Other revenues and Other income include additional gains from product divestments; Cost of goods sold and Other expense include charges for the Group-wide rationalization of manufacturing sites; Cost of goods sold also includes an inventory write-off; Marketing & Sales, Research & Development and Other expense include other restructuring charges; Research & Development also includes expenses related to product acquisitions; General & Administration includes charges for transforming IT and finance processes and expenses related to setup costs for Novartis Business Services; Other income also includes a gain of $110 million from a Swiss pension plan amendment and items related to portfolio transformation; Other expense also includes legal settlement provisions; Income from associated companies includes $292 million for the Novartis share of the estimated OTC joint venture core items; Other financial income and expense relates mainly to devaluation losses in Venezuela.

(5)

Taxes on the adjustments between IFRS and core results take into account, for each individual item included in the adjustment, the tax rate that will finally be applicable to the item based on the jurisdiction where the adjustment will finally have a tax impact. Generally, this results in amortization and impairment of intangible assets and acquisition-related restructuring and integration items having a full tax impact. There is usually a tax impact on other items, although this is not always the case for items arising from legal settlements in certain jurisdictions. Adjustments related to income from associated companies are recorded net of any related tax effect. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments for continuing operations of $6.0 billion to arrive at the core results before tax amounts to $945 million. The average tax rate on the adjustments for continuing operations is 15.9%.

(6)

For details on discontinued operations reconciliation from IFRS to core net income, please refer to " 2015 and 2014 Reconciliation of IFRS Results to Core Results Discontinued Operations".

(7)

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

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

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

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

(3)

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

(4)

Other items: Other revenues includes an amount for a commercial settlement; Cost of goods sold includes charges for the Group-wide rationalization of manufacturing sites; Marketing & Sales, Research & Development and General & Administration include charges for transforming IT and finance processes; Other income includes product related divestment gains and gains in the Novartis Venture Fund, an insurance recovery net of a deferred amount, a partial reversal of a legal expense provision, a reduction in restructuring provisions, and the impact from a post-retirement medical plan amendment; Other expense includes restructuring provision charges, charges for transforming IT and finance processes, an expense related to *Lucentis* in Italy, the expense of $204 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations; Income from associated companies includes gains from the divestment of Idenix and LTS Lohmann Therapie-Systeme AG shareholdings.

(5)

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

(6)

For details on discontinued operations reconciliation from IFRS to core net income, please refer to " 2015 and 2014 Reconciliation of IFRS Results to Core Results Discontinued Operations".

(7)

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

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**2016, 2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS INNOVATIVE MEDICINES (FORMERLY NAMED THE PHARMACEUTICALS DIVISION)**

| 2016 | IFRS results | Amortization of intangible assets[1] | Impairments[2] | Acquisition or divestment related items, including restructuring and integration charges[3] | Other items[4] | Core results |
|---|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **24,670** | **2,409** | **41** | | **(11)** | **27,109** |
| **Operating income** | **7,426** | **2,440** | **617** | **(27)** | **(102)** | **10,354** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | | |
| Other revenues | 815 | | | | (50) | 765 |
| Cost of goods sold | (9,331) | 2,409 | 41 | | 39 | (6,842) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | | |
| Marketing & Sales | (8,435) | | | | 7 | (8,428) |
| Research & Development | (7,709) | 31 | 481 | | 85 | (7,112) |
| Other income | 1,091 | | | (68) | (759) | 264 |
| Other expense | (1,213) | | 95 | 41 | 576 | (501) |

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

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

(3) Acquisition or divestment related items, including restructuring and integration charges: Other income and Other expense include transitional service-fee income and expenses and other items related to the portfolio transformation; Other income also includes a gain from the revaluation of a previously held financial investment in a newly acquired company.

(4) Other items: Other revenues include an early release of deferred income associated with a collaboration agreement; Cost of goods sold, Other income and Other expense include net restructuring and other charges related to the Group-wide rationalization of manufacturing sites; Research & Development, Marketing & Sales, Other income and Other expense include other restructuring income and charges; Research & Development also includes an expense due to an adjustment of a contingent consideration; Other income and Other expense also include legal settlements and changes in provisions; Other income also includes gains from product divestments; Other expense also includes a charge as a result of a pension plan amendment.

| 2015 | IFRS restated results[1] | Amortization of intangible assets[2] | Impairments[3] | Acquisition or divestment related items, including restructuring and integration charges[4] | Other items[5] | Core restated results[1] |
|---|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **25,451** | **2,335** | **99** | | **90** | **27,975** |
| **Operating income** | **7,815** | **2,367** | **131** | **192** | **357** | **10,862** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Other revenues | 792 | | | | (28) | 764 |
| Cost of goods sold | (9,204) | 2,335 | 99 | | 118 | (6,652) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | | |
| Marketing & Sales | (8,430) | | | | 43 | (8,387) |
| Research & Development | (7,685) | 32 | 39 | | 112 | (7,502) |
| Other income | 1,149 | | (56) | (22) | (747) | 324 |
| Other expense | (1,639) | | 49 | 214 | 859 | (517) |

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

(2) 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.

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

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

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

| **2014** | **IFRS restated results[1]** | **Amortization of intangible assets[2]** | **Impairments[3]** | **Acquisition or divestment related items, including restructuring and integration charges[4]** | **Other items[5]** | **Core restated results[1]** |
|---|---|---|---|---|---|---|
| | **$ m** | **$ m** | **$ m** | **$ m** | **$ m** | **$ m** |
| **Gross profit** | **27,433** | **1,359** | **(58)** | | **127** | **28,861** |
| **Operating income** | **8,826** | **1,401** | **273** | **33** | **542** | **11,075** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | | |
| Cost of goods sold | (8,724) | 1,359 | (58) | | 127 | (7,296) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | | |
| Marketing & Sales | (8,809) | | | | 8 | (8,801) |
| Research & Development | (7,787) | 42 | 296 | | 17 | (7,432) |
| General & Administration | (1,114) | | | | 1 | (1,113) |
| Other income | 737 | | (13) | | (454) | 270 |
| Other expense | (1,634) | | 48 | 33 | 843 | (710) |

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

(2) 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.

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

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

(5) Other items: Cost of goods sold, Research & Development and Marketing & Sales include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Marketing & Sales also includes charges for transforming IT and finance processes; Research & Development also includes a net increase of contingent consideration liabilities related to acquisitions; Other income includes an insurance recovery from Corporate related to exchange risks, gains related to the rationalization of manufacturing sites, the impact from a post-retirement medical plan amendment, as well as additional gains from divestments announced in prior periods; Other expense include restructuring charges, an expense related to *Lucentis* in Italy and an expense of $186 million related to the advancement of the timing of recording the US Healthcare Fee liability as a result of final regulations.

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**2016, 2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS SANDOZ**

| 2016 | IFRS results | Amortization of intangible assets[1] | Impairments[2] | Other items[3] | Core results |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **4,314** | **460** | **55** | **60** | **4,889** |
| **Operating income** | **1,445** | **460** | **66** | **100** | **2,071** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (5,971) | 460 | 55 | 60 | (5,396) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Research & Development | (814) | | 10 | | (804) |
| Other income | 185 | | (10) | (29) | 146 |
| Other expense | (259) | | 11 | 69 | (179) |

(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.

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

(3) 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, Other income and Other expense also include other restructuring income and charges; Other income also includes gains from product divestments; Other expense also includes other costs.

| 2015 | IFRS restated results[1] | Amortization of intangible assets[2] | Impairments[3] | Acquisition or divestment related items, including restructuring and integration charges[4] | Other items[5] | Core restated results[1] |
|---|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **4,379** | **446** | **27** | | **33** | **4,885** |
| **Operating income** | **1,300** | **447** | **124** | | **174** | **2,045** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | | |
| Cost of goods sold | (5,844) | 446 | 27 | | 33 | (5,338) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | | |
| Research & Development | (782) | 1 | | | | (781) |
| Other income | 109 | | | (1) | (4) | 104 |
| Other expense | (381) | | 97 | 1 | 145 | (138) |

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

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

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

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

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

| 2014 | IFRS restated results[1] | Amortization of intangible assets[2] | Impairments[3] | Other items[4] | Core restated results[1] |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **4,742** | **446** | **37** | **10** | **5,235** |
| **Operating income** | **1,570** | **448** | **47** | **36** | **2,101** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (6,293) | 446 | 37 | 10 | (5,800) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Research & Development | (833) | 2 | 2 | | (829) |
| Other income | 97 | | (1) | (3) | 93 |
| Other expense | (189) | | 9 | 29 | (151) |

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

(2) 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.

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

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

**2016, 2015 AND 2014 RECONCILIATION OF IFRS RESULTS TO CORE RESULTS ALCON**

| 2016 | IFRS results | Amortization of intangible assets[1] | Impairments[2] | Other items[3] | Core results |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **2,724** | **889** | | **(13)** | **3,600** |
| **Operating loss/income** | **(132)** | **901** | **4** | **77** | **850** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (3,092) | 889 | | (13) | (2,216) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Research & Development | (516) | 12 | 4 | 14 | (486) |
| Other income | 48 | | | (4) | 44 |
| Other expense | (96) | | | 80 | (16) |

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

(2) Impairments: Research & Development includes impairment charges related to intangible assets.

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(3) Other items: Cost of goods sold includes an income due to an adjustment of a contingent consideration; Research & Development, Other income and Other expense include restructuring income and charges; Research & Development also includes an expense due to an adjustment of a contingent consideration; Other expense also includes a charge for an indirect tax settlement.

| 2015 | IFRS restated results[1] | Amortization of intangible assets[2] | Impairments[3] | Other items[4] | Core restated results[1] |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **2,877** | **885** | | **2** | **3,764** |
| **Operating income** | **281** | **895** | **2** | **57** | **1,235** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (3,145) | 885 | | 2 | (2,258) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Research & Development | (468) | 10 | 1 | 2 | (455) |
| General & Administration | (450) | | | 32 | (418) |
| Other income | 54 | | | (9) | 45 |
| Other expense | (69) | | 1 | 30 | (38) |

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

(2) 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.

(3) Impairments: Research & Development includes impairment charges related to intangible assets; Other expense includes impairment charges related to property, plant and equipment.

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

| 2014 | IFRS restated results[1] | Amortization of intangible assets[2] | Impairments[3] | Other items[4] | Core restated results[1] |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **3,444** | **887** | | **26** | **4,357** |
| **Operating income** | **760** | **891** | **(1)** | **70** | **1,720** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (3,204) | 887 | | 26 | (2,291) |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Marketing & Sales | (1,697) | | | 14 | (1,683) |
| Research & Development | (466) | 4 | | | (462) |
| General & Administration | (508) | | | 45 | (463) |
| Other income | 76 | | (1) | (49) | 26 |
| Other expense | (89) | | | 34 | (55) |

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

(2) 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.

(3) Impairments: Other income includes a reversal of impairment charges related to property, plant and equipment.

(4) Other items: Cost of goods sold and Other expense include net restructuring charges related to the Group-wide rationalization of manufacturing sites; Marketing & Sales and General & Administration include charges for transforming IT and finance processes; Other income includes the reversal of restructuring charges related to the Group-wide rationalization of manufacturing sites, as well as the impact from a post-retirement medical plan amendment.

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**2016, 2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS CORPORATE**

| 2016 | IFRS results | Impairments[1] | Acquisition or divestment related items, including restructuring and integration charges[2] | Other items[3] | Core results |
|---|---|---|---|---|---|
| | $ m | $ m | $ m | $ m | $ m |
| **Gross profit** | **208** | | | | **208** |
| **Operating loss** | **(471)** | **99** | **(6)** | **90** | **(288)** |
| **The following are adjustments to arrive at Core Operating Loss** | | | | | |
| General & Administration | (506) | | | 74 | (432) |
| Other income | 603 | | (229) | (75) | 299 |
| Other expense | (776) | 99 | 223 | 91 | (363) |

(1) Impairments: Other expense includes impairment charges related to financial assets.

(2) Acquisition or divestment 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.

(3) Other items: General & Administration, Other income and Other expense include items related to setup costs for Novartis Business Services; Other income also includes an income related to the portfolio transformation and a gain related to the sale of real estate; Other expense also includes other restructuring charges and other costs.

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

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

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

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

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

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

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

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

**2015 AND 2014 RECONCILIATION FROM IFRS RESULTS TO CORE RESULTS GROUP DISCONTINUED OPERATIONS**

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

| | | | | | |
|---|---|---|---|---|---|
| **EPS ($)[5]** | **4.48** | | | | **(0.11)** |
| | | | | | |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | |
| Cost of goods sold | (376) | | | 6 | (370) |
| | | | | | |
| **The following are adjustments to arrive at Core Operating Income** | | | | | |
| Other income | 13,420 | | (13,310) | (1) | 109 |
| Other expense | (727) | (83) | 683 | 3 | (124) |

(1) Impairments: Other expense includes the partial reversal of the influenza Vaccines business impairment charge recorded in 2014.

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(2) Acquisition or divestment related items, including restructuring and integration charges: Other income includes gains from the divestment of Animal Health ($4.6 billion) and from the transactions with GSK ($2.8 billion for the non-influenza Vaccines business and $5.9 billion resulting from the contribution of the former Novartis OTC Division into the GSK consumer healthcare joint venture in exchange for 36.5% interest in this newly created entity); Other expense includes additional transaction related expenses of $0.6 billion and other portfolio transformation related costs.

(3) Other items: Cost of goods sold, Other income and Other expense include restructuring charges.

(4) 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. There is usually a tax impact on other items although this is not always the case for items arising from legal settlements in certain jurisdictions. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of $12.7 billion to arrive at the core results before tax amounts to $1.7 billion. The average tax rate on the adjustments is 13.2%.

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

| **2014** | **IFRS results** | **Amortization of intangible assets[1]** | **Impairments[2]** | **Acquisition or divestment related items, including restructuring and integration charges[3]** | **Other items[4]** | **Core results** |
|---|---|---|---|---|---|---|
| | **$ m** | **$ m** | **$ m** | **$ m** | **$ m** | **$ m** |
| **Gross profit** | **2,886** | **65** | **302** | | **19** | **3,272** |
| **Operating loss/income** | **(353)** | **73** | **1,141** | **(680)** | **(38)** | **143** |
| **Loss/income before taxes** | **(351)** | **73** | **1,141** | **(680)** | **(38)** | **145** |
| Taxes[5] | (96) | | | | | (43) |
| **Net loss/income** | **(447)** | | | | | **102** |
| **EPS ($)[6]** | **(0.18)** | | | | | **0.04** |
| **The following are adjustments to arrive at Core Gross Profit** | | | | | | |
| Cost of goods sold | (3,073) | 65 | 302 | | 19 | (2,687) |
| **The following are adjustments to arrive at Core Operating Loss** | | | | | | |
| Research & Development | (857) | 8 | | | | (849) |
| Other income | 1,007 | | (1) | (876) | (89) | 41 |
| Other expense | (1,146) | | 840 | 196 | 32 | (78) |

(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 up to the portfolio transformation annoucement date; Research & Development includes the recurring amortization of acquired rights for technology platforms up to the portfolio transformation announcement date.

(2)

Impairments: Cost of goods sold and Other expense include the $1.1 billion impairment charge as a result of the sale of the influenza vaccines business; Other income includes a reduction of an impairment charge for property, plant and equipment; Other expense relates to an additional impairment charge in Corporate, for an in-process project which is divestment as a result of the portfolio transformation transactions.

(3)

Acquisition or divestment related items, including restructuring and integration charges: Other income includes the gain on the disposal of the blood transfusion diagnostics unit on January 9, 2014; Other expense includes professional service fees related to the portfolio transformation divestment activities.

(4)

Other items: Cost of goods sold and Other expense include restructuring charges related to the Group-wide rationalization of manufacturing sites; Other income includes the gain on the sale of a divested product, which was sold as a result of the portfolio transformation transaction, the reversal of restructuring charges related to the Group-wide rationalization of manufacturing sites, the partial reversal of a legal expense provision, and the impact from a post-retirement medical plan amendment; Other expense also includes the write-off of a receivable as a result of the portfolio transformation transactions.

(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. There is usually a tax impact on other items although this is not always the case for items arising from legal settlements in certain jurisdictions. Due to these factors and the differing effective tax rates in the various jurisdictions, the tax on the total adjustments of $496 million to arrive at the core results before tax amounts to $53 million. The average tax rate on the adjustments is 10.7%.

(6)

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

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**5.B Liquidity and Capital Resources**

The following tables summarize the Group's cash flow and net debt.

| | 2016 | 2015 | 2014 |
|---|---|---|---|
| | $ m | $ m | $ m |
| Cash flows from operating activities from continuing operations | 11,475 | 12,085 | 13,898 |
| Cash flows used in investing activities from continuing operations | (2,693) | (19,666) | (8) |
| Cash flows used in/from operating and investing activities from discontinued operations | (748) | 8,694 | 888 |
| Cash flows used in financing activities | (5,314) | (9,176) | (8,147) |
| Effect of exchange rate changes on cash and cash equivalents | (387) | (286) | (295) |
| **Net change in cash and cash equivalents** | **2,333** | **(8,349)** | **6,336** |
| Change in marketable securities, commodities, time deposits and derivative financial instruments | (3) | (66) | (1,696) |
| Change in current and non-current financial debts and derivative financial instruments | (1,871) | (1,520) | (2,393) |
| **Change in net debt** | **459** | **(9,935)** | **2,247** |
| Net debt at January 1 | (16,484) | (6,549) | (8,796) |
| **Net debt at December 31** | **(16,025)** | **(16,484)** | **(6,549)** |

**CASH FLOW**

***Financial year 2016***

Cash flows from operating activities from continuing operations amounted to $11.5 billion, compared to $12.1 billion in 2015. The decrease of $0.6 billion was driven by lower operating income adjusted for non-cash items, lower hedging results and higher payments out of provisions, partially offset by dividends received from GSK Consumer Healthcare Holdings Ltd., lower cash outflows for taxes paid and net current assets and other operating cash flow items.

Cash flows used in investing activities from continuing operations amounted to $2.7 billion in 2016. This amount includes cash outflows of $1.9 billion for the purchase of property, plant and equipment, $1.4 billion for intangible, financial and other non-current assets, and $0.8 billion for acquisitions and divestments of businesses, net (including the Transcend Medical, Inc. and Selexys Pharmaceuticals Corporation acquisitions). This was offset by cash inflows of $1.3 billion of proceeds from the sale of non-current assets and $0.1 billion net proceeds from sales of marketable securities and commodities. In 2015, cash flows used in investing activities from continuing operations amounted to $19.7 billion, primarily due to the acquisition of the GSK oncology assets for $16.0 billion.

Cash flows used in investing activities from discontinued operations amounted to $0.7 billion in 2016 due to portfolio transformation transactions payments, including capital gains taxes. In 2015, the cash flows from investing activities from discontinued operations of $8.9 billion were mainly driven by net proceeds from the portfolio transformation divestments.

The cash flows used in financing activities amounted to $5.3 billion, compared to $9.2 billion in 2015. The 2016 amount includes cash outflows of $6.5 billion for the dividend payment and $0.9 billion for treasury share transactions, net. The net inflow from current and non-current financial debts of $2.1 billion was due to the increase in short-term borrowings of $1.8 billion and the issuance of two euro denominated bonds for total proceeds of $1.9 billion, partially offset by the repayment at maturity of a euro denominated bond of $1.7 billion.

The 2015 amount included mainly a cash outflow of $6.6 billion for the dividend payment and $4.5 billion for treasury share transactions, net, partially offset by a net inflow from financial debts of $2.0 billion.

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***Financial year 2015***

Cash flow from operating activities of continuing operations decreased to $12.1 billion from $13.9 billion in 2014.

The decrease was primarily due to the negative currency impact on operations. The prior year also included higher proceeds from commercial settlements.

The cash outflow for investing activities of continuing operations amounted to $19.7 billion in 2015. This was primarily due to the outflow of $16.5 billion for acquisitions of businesses, mainly the oncology business from GSK for $16.0 billion, the net outflow of $2.8 billion for the purchase of property, plant and equipment, intangible and other non-current assets and the net outflow of $0.3 billion from the change in marketable securities.

In 2014, cash flow from investing activities of continuing operations was a small net outflow of $8 million. This was primarily due to net outflows of $0.3 billion from the acquisition of businesses, $3.0 billion mainly from purchase of property, plant and equipment, offset by $1.4 billion of proceeds from the sale of investments in associated companies, particularly LTS Lohmann Therapie-Systeme AG and Idenix Pharmaceuticals, Inc. and $1.9 billion proceeds from the net sale of other marketable securities, including maturing long-term deposits.

The cash flows used in financing activities amounted to $9.2 billion, compared to $8.1 billion in 2014. The 2015 amount includes a cash outflow of $6.6 billion for the dividend payment and $4.5 billion for treasury share transactions, net. The net inflow from the increase in current and non-current financial debt of $2.0 billion was mainly due to the issuance of three Swiss franc denominated bonds for a total amount of $1.5 billion in the first half of 2015, the issuance of two US dollar denominated bonds totaling $3.0 billion in the fourth quarter 2015 and the increase in commercial paper outstanding of $0.4 billion, partially offset by the repayment at maturity of a US dollar denominated bond of $2.0 billion and a Swiss franc denominated bond of $0.9 billion. In 2014, the cash outflows included $6.8 billion for the dividend payment and $4.5 billion for treasury share transactions, net. These outflows were partially offset by increase in the current and non-current financial debt of $3.3 billion.

The net cash inflows from discontinued operations of $8.7 billion in 2015 were mainly driven by the net proceeds of $8.9 billion from the divestments in connection with the portfolio transformation transactions. In 2014, the net cash inflow of $0.9 billion consisted mainly of proceeds from the divestment of the blood transfusion diagnostics unit to Grifols S.A.

***Financial year 2014***

Cash flow from operating activities of continuing operations increased to $13.9 billion from $12.6 billion in 2013, an increase of $1.3 billion. This was primarily due to higher operating income adjusted for non-cash items, despite negative currency effects and increased hedging gains, partially offset by payments for legal settlements and restructuring.

The cash flow used in investing activities from continuing operations were almost balanced compared to an outflow of $3.2 billion in 2013. In 2014, there were proceeds from the sale of investments in associated companies included, in particular LTS Lohmann Therapie-Systeme AG and Idenix Pharmaceuticals, Inc. of $0.6 billion and $0.8 billion respectively and of $1.9 billion from the net sale of other marketable securities including maturing long-term deposits. These inflows were offset by outflows of $2.6 billion for property, plant and equipment and a net amount of $0.7 billion for acquisition of businesses mainly the acquisition of WaveTec ($0.4 billion) and other non-current assets, primarily intangible assets. The prior year outflow for investing activities of $3.2 billion was primarily related to investments in property, plant and equipment of $2.9 billion and a net outflow of $0.3 billion for the acquisition of businesses and other non-current assets, mainly intangible assets.

In 2014, cash inflows from investing activities of discontinued operations amounted to $ 0.9 billion, mainly on account of the net proceeds from the divestment of the blood transfusion diagnostics unit to Grifols S.A.

The Group total cash flows used in financing activities amounted to $8.1 billion, compared to $8.8 billion, in 2013. The 2014 amount includes the dividend payment of $6.8 billion, net treasury share transactions of $4.5 billion and a net increase in financial debt of $3.3 billion, principally due to the issuance of four bonds totaling $5.5 billion reduced by the repayment at maturity of a bond of $2.0 billion. In 2013, the dividend payment amounted to $6.1 billion, net treasury share transactions were $1.2 billion and financial debt decreased by a net amount of $1.3 billion.

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**GROUP NET DEBT**

Net debt constitutes a non-IFRS financial measure, which means that it should not be interpreted as a measure determined under International Financial Reporting Standards (IFRS). Net debt/liquidity is presented as additional information as it is a useful indicator of the Group's ability to meet financial commitments and to invest in new strategic opportunities, including strengthening its balance sheet.

Group net debt consists of:

| | 2016 | 2015 | Change |
|---|---|---|---|
| | $ m | $ m | $ m |
| Current financial debts and derivative financial instruments | (5,905) | (5,604) | (301) |
| Non-current financial debts | (17,897) | (16,327) | (1,570) |
| **Total financial debt** | **(23,802)** | **(21,931)** | **(1,871)** |
| Less liquidity | | | |
| Cash and cash equivalents | 7,007 | 4,674 | 2,333 |
| Marketable securities, commodities, time deposits and derivative financial instruments | 770 | 773 | (3) |
| **Total liquidity** | **7,777** | **5,447** | **2,330** |
| **Net debt at December 31** | **(16,025)** | **(16,484)** | **459** |

***Financial year 2016***

Total non-current and current financial debt, including derivatives, amounted to $23.8 billion at December 31, 2016, compared to $21.9 billion at December 31, 2015.

Non-current financial debt increased by $1.6 billion to $17.9 billion at December 31, 2016, mainly due to the issuance of two euro denominated bonds for a total amount of $2.0 billion.

Current financial debt increased by $0.3 billion to $5.9 billion at December 31, 2016, from $5.6 billion at December 31, 2015, mainly due to higher short-term borrowings partially offset by a repayment at maturity of a euro denominated bond of $1.7 billion. Overall current financial debt consists of the current portion of non-current debt of $0.2 billion and other short-term borrowings (including derivatives and commercial paper) of $5.7 billion. Group net debt decreased to $16.0 billion at the end of 2016 from $16.5 billion at the end of 2015.

Novartis has two US commercial paper programs under which it can issue up to $9.0 billion in the aggregate of unsecured commercial paper notes. Novartis also has a Japanese commercial paper program under which it can issue up to JPY 150 billion (approximately $1.3 billion) of unsecured commercial paper notes. Commercial paper notes totaling $3.2 billion under these three programs were outstanding as per December 31, 2016. Novartis further has a committed credit facility of $6.0 billion, entered into on September 23, 2015. This credit facility is provided by a syndicate of banks and is intended to be used as a backstop for the US commercial paper programs. It matures in September 2020 and was undrawn as per December 31, 2016.

The long-term credit rating for the company continues to be double-A (Moody's Aa3; Standard & Poor's AA ; Fitch AA).

***Financial year 2015***

Total financial debt, including derivatives, amounted to $21.9 billion at December 31, 2015 compared to $20.4 billion at December 31, 2014.

Non-current financial debt increased by $2.5 billion to $16.3 billion at December 31, 2015, from $13.8 billion at December 31, 2014. The increase was mainly due to the issuance of three Swiss franc denominated bonds for a total amount of $1.5 billion and the issuance of two US dollar denominated bonds for a total of $3.0 billion, partially offset by the reclassification to current financial debt of a euro denominated bond

of $1.6 billion.

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Current financial debt decreased by $1.0 billion to $5.6 billion at December 31, 2015, from $6.6 billion at December 31, 2014. The decrease was mainly due to repayment at maturity of a US dollar denominated bond of $2.0 billion and a Swiss franc denominated bond of $0.9 billion, partially offset by the reclassification from non-current financial debt of the $1.6 billion euro denominated bond mentioned above.

Overall current financial debt consists of the current portion of non-current debt of $1.7 billion and other short-term borrowings (including derivatives and commercial paper) of $3.9 billion. Group net debt increased to $16.5 billion at the end of 2015 compared to $6.5 billion at the end of 2014.

Novartis has two US commercial paper programs under which it can issue up to $9 billion in the aggregate of unsecured commercial paper notes. Novartis also has a Japanese commercial paper program under which it can issue up to JPY 150 billion (approximately $1.25 billion) of unsecured commercial paper notes. Commercial paper notes totaling $1.1 billion under these three programs were outstanding as per December 31, 2015. Novartis further has a committed credit facility of $6 billion, entered into on September 23, 2015. This credit facility is provided by a syndicate of banks and is intended to be used as a backstop for the US commercial paper programs. It matures in September 2020 and was undrawn as per December 31, 2015.

The long-term credit rating for the company continues to be double-A (Moody's Aa3; Standard & Poor's AA ; Fitch AA).

An overview of the movements in our current financial debt and related interest rates is set forth below:

| | December 31 | Average interest rate at year end | Average balance during the year | Average interest rate during the year | Maximum balance during the year |
|---|---|---|---|---|---|
| | $ m | % | $ m | % | $ m |
| **2016** | | | | | |
| Interest-bearing accounts of associates payable on demand | 1,601 | 0.50 | 1,694 | 0.50 | 1,763 |
| Bank and other financial debt | 836 | 8.56 | 1,066 | 6.71 | 1,369 |
| Commercial paper | 3,174 | 0.68 | 4,788 | 0.45 | 6,989 |
| Current portion of non-current financial debt | 178 | na | 881 | na | 1,719 |
| Fair value of derivative financial instruments | 116 | na | 93 | na | 192 |
| **Total current financial debt** | **5,905** | | **8,522** | | **12,032** |
| **2015** | | | | | |
| Interest-bearing accounts of associates payable on demand | 1,645 | 0.62 | 1,720 | 0.59 | 1,803 |
| Bank and other financial debt | 1,185 | 5.98 | 1,280 | 5.54 | 2,785 |
| Commercial paper | 1,085 | 0.62 | 3,545 | 0.19 | 5,686 |
| Current portion of non-current financial debt | 1,659 | na | 1,916 | na | 3,044 |
| Fair value of derivative financial instruments | 30 | na | 79 | na | 188 |
| **Total current financial debt** | **5,604** | | **8,540** | | **13,506** |

na = not applicable or available

Interest bearing accounts of associates payable on demand relate to employee deposits in CHF from the compensation of associates employed by Swiss entities (December 31, 2016 interest rate: 0.5%). Other bank and financial debt refer to usual lending and overdraft facilities.

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The maturity schedule of our net debt is as follows:

| | 2016 | | | | | |
|---|---|---|---|---|---|---|
| | Due within one month | Due later than one month but less than three months | Due later than three months but less than one year | Due later than one year but less than five years | Due after five years | Total |
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Current assets** | | | | | | |
| Marketable securities and time deposits | 32 | 126 | 110 | 124 | 53 | 445 |
| Commodities | | | | | 94 | 94 |
| Derivative financial instruments and accrued interest | 38 | 102 | 91 | | | 231 |
| Cash and cash equivalents | 5,907 | 1,100 | | | | 7,007 |
| **Total current financial assets** | **5,977** | **1,328** | **201** | **124** | **147** | **7,777** |
| **Non-current liabilities** | | | | | | |
| Financial debt | | | | (5,141) | (12,756) | (17,897) |
| *Financial debt undiscounted* | | | | *(5,155)* | *(12,901)* | *(18,056)* |
| **Total non-current financial debt** | | | | **(5,141)** | **(12,756)** | **(17,897)** |
| **Current liabilities** | | | | | | |
| Financial debt | (5,099) | (250) | (440) | | | (5,789) |
| *Financial debt undiscounted* | *(5,099)* | *(250)* | *(440)* | | | *(5,789)* |
| Derivative financial instruments | (15) | (72) | (29) | | | (116) |
| **Total current financial debt** | **(5,114)** | **(322)** | **(469)** | | | **(5,905)** |
| **Net debt** | **863** | **1,006** | **(268)** | **(5,017)** | **(12,609)** | **(16,025)** |

| | 2015 | | | | | |
|---|---|---|---|---|---|---|
| | Due within one month | Due later than one month but less than three months | Due later than three months but less than one year | Due later than one year but less than five years | Due after five years | Total |
| | $ m | $ m | $ m | $ m | $ m | $ m |
| **Current assets** | | | | | | |
| Marketable securities and time deposits | 22 | 11 | 200 | 247 | 62 | 542 |
| Commodities | | | | | 86 | 86 |
| Derivative financial instruments and accrued interest | 40 | 67 | 38 | | | 145 |
| Cash and cash equivalents | 4,674 | | | | | 4,674 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Total current financial assets** | **4,736** | **78** | **238** | **247** | **148** | **5,447** |
| **Non-current liabilities** | | | | | | |
| Financial debt | | | | (4,664) | (11,663) | (16,327) |
| *Financial debt undiscounted* | | | | *(4,676)* | *(11,797)* | *(16,473)* |
| **Total non-current financial debt** | | | | **(4,664)** | **(11,663)** | **(16,327)** |
| **Current liabilities** | | | | | | |
| Financial debt | (3,258) | (289) | (2,027) | | | (5,574) |
| *Financial debt undiscounted* | *(3,258)* | *(289)* | *(2,028)* | | | *(5,575)* |
| Derivative financial instruments | (8) | (20) | (2) | | | (30) |
| **Total current financial debt** | **(3,266)** | **(309)** | **(2,029)** | | | **(5,604)** |
| **Net debt** | **1,470** | **(231)** | **(1,791)** | **(4,417)** | **(11,515)** | **(16,484)** |

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The following table provides a breakdown of liquidity and financial debt by currency as of December 31:

**LIQUIDITY AND FINANCIAL DEBT BY CURRENCY**

| | Liquidity in % 2016[1] | Liquidity in % 2015[1] | Financial debt in % 2016[2] | Financial debt in % 2015[2] |
|---|---|---|---|---|
| $ | 77 | 50 | 66 | 64 |
| EUR | 9 | 16 | 13 | 14 |
| CHF | 5 | 13 | 13 | 14 |
| JPY | | 1 | 5 | 5 |
| Other | 9 | 20 | 3 | 3 |
| | 100 | 100 | 100 | 100 |

(1) Liquidity includes cash and cash equivalents, marketable securities, commodities and time deposits.

(2) Financial debt includes non-current and current financial debt.

**EFFECTS OF CURRENCY FLUCTUATIONS**

We transact our business in many currencies other than the US dollar, our reporting currency.

The following provides an overview of net sales and operating expenses for our continuing operations based on IFRS values for 2016, 2015 and 2014 for currencies most important to the Group:

| | 2016 | | 2015 | | 2014 | |
|---|---|---|---|---|---|---|
| Currency | Net sales | Operating expenses | Net sales | Operating expenses | Net sales | Operating expenses |
| | % | % | % | % | % | % |
| US dollar ($) | 38 | 43 | 40 | 42 | 36 | 39 |
| Euro (EUR) | 26 | 23 | 24 | 23 | 26 | 25 |
| Swiss franc (CHF) | 2 | 15 | 2 | 13 | 2 | 13 |
| Japanese yen (JPY) | 7 | 5 | 6 | 4 | 7 | 5 |
| Chinese yuan (CNY) | 4 | 3 | 4 | 3 | 3 | 3 |
| British pound (GBP) | 3 | 2 | 3 | 3 | 3 | 2 |
| Canadian dollar (CAD) | 3 | 1 | 3 | 1 | 3 | 1 |
| Brazilian real (BRL) | 2 | 1 | 2 | 2 | 2 | 2 |
| Australian dollar (AUD) | 2 | 1 | 2 | 1 | 2 | 1 |
| Russian ruble (RUB) | 1 | 1 | 1 | 1 | 2 | 1 |
| Other currencies | 12 | 5 | 13 | 7 | 14 | 8 |

Operating expenses in the above table include cost of goods sold, Marketing & Sales, Research & Development, General & Administration, Other income and Other expense.

We prepare our consolidated financial statements in US dollars. As a result, fluctuations in the exchange rates between the US dollar and other currencies can have a significant effect on both the Group's results of operations as well as on the reported value of our assets, liabilities and cash flows. This in turn may significantly affect reported earnings (both positively and negatively) and the comparability of period-to-period results of operations.

For purposes of our consolidated balance sheets, we translate assets and liabilities denominated in other currencies into US dollars at the prevailing market exchange rates as of the relevant balance sheet date. For purposes of the Group's consolidated income and cash flow statements, revenue, expense and cash flow items in local currencies are translated into US dollars at average exchange rates prevailing during the relevant period. As a result, even if the amounts or values of these items remain unchanged in the respective local currency, changes

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in exchange rates have an impact on the amounts or values of these items in our consolidated financial statements.

Because our expenditures in Swiss francs are significantly higher than our revenues in Swiss francs, volatility in the value of the Swiss franc can have a significant impact on the reported value of our earnings, assets and liabilities, and the timing and extent of such volatility can be difficult to predict. In addition, there is a risk that certain countries could take steps that could significantly impact the value of their currencies.

There is also a risk that certain countries could devalue their currency. If this occurs, then it could impact the effective prices we would be able to charge for our products and also have an adverse impact on both our consolidated income statement and balance sheet. The Group is exposed to a potential adverse devaluation risk on its intercompany funding and total investment in certain subsidiaries operating in countries with exchange controls.

The most significant country in this respect is Venezuela, where the Group has incurred significant foreign exchange losses in 2016 and 2015.

Subsidiaries whose functional currencies have experienced a cumulative inflation rate of more than 100% over the past three years apply the rules of IAS 29 "Financial Reporting in Hyperinflationary Economies." Gains and losses incurred upon adjusting the carrying amounts of non-monetary assets and liabilities for inflation are recognized in the income statement. The subsidiaries in Venezuela restate non-monetary items in the balance sheet in line with the requirements of IAS 29.

The Group's subsidiaries in Venezuela are experiencing a significant reduction in approvals for remittance of US dollars outside the country at the exchange rate available for imports of specific goods and services of national priority, including medicines and medical supplies. As a result, in November 2016, the Group changed the exchange rate applied to translate the financial statements of its Venezuelan subsidiaries from VEF 11 per $ to the floating rate of DICOM (Sistema de Divisa Complementaria) which was VEF 658 per $ as of November 1, 2016. A corresponding $0.3 billion revaluation loss on the outstanding intercompany balances was recognized in the fourth quarter of 2016. Due to reserves against the intercompany balances, the net outstanding intercompany payable balance of Venezuela subsidiaries was reduced to an insignificant amount as at December 31, 2016.

The Group has an equivalent of approximately $2 million of cash in Venezuela in local currency (VEF), which is subject to loss of purchase power due to high inflation in the country.

The Group manages its global currency exposure by engaging in hedging transactions where management deems appropriate, after taking into account the natural hedging afforded by our global business activity. For 2016, we entered into various contracts that change in value with movements in foreign exchange rates to preserve the value of assets, commitments and expected transactions. We use forward contracts and foreign currency options to hedge. For more information on how these transactions affect our consolidated financial statements and on how foreign exchange rate exposure is managed, see "Note 1. Significant Accounting Policies", "Note 5. Interest Expense and other Financial Income and Expense", "Note 16. Marketable Securities, Commodities, Time Deposits, Derivative Financial Instruments and Cash and Cash Equivalents" and "Note 29. Financial Instruments  Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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The following table sets forth the foreign exchange rates of the US dollar against key currencies used for foreign currency translation when preparing the Group's consolidated financial statements:

| | Average for year | | Change | Year-end | | Change |
|---|---|---|---|---|---|---|
| **$ per unit** | **2016** | **2015** | **in %** | **2016** | **2015** | **in %** |
| AUD | 0.744 | 0.753 | (1) | 0.722 | 0.731 | (1) |
| BRL | 0.288 | 0.305 | (6) | 0.307 | 0.253 | 21 |
| CAD | 0.755 | 0.784 | (4) | 0.741 | 0.721 | 3 |
| CHF | 1.015 | 1.040 | (2) | 0.978 | 1.011 | (3) |
| CNY | 0.151 | 0.159 | (5) | 0.144 | 0.154 | (6) |
| EUR | 1.107 | 1.110 | 0 | 1.051 | 1.093 | (4) |
| GBP | 1.355 | 1.529 | (11) | 1.227 | 1.483 | (17) |
| JPY (100) | 0.922 | 0.826 | 12 | 0.854 | 0.831 | 3 |
| RUB (100) | 1.498 | 1.649 | (9) | 1.648 | 1.362 | 21 |

| | Average for year | | Change | Year-end | | Change |
|---|---|---|---|---|---|---|
| **$ per unit** | **2015** | **2014** | **in %** | **2015** | **2014** | **in %** |
| AUD | 0.753 | 0.903 | (17) | 0.731 | 0.819 | (11) |
| BRL | 0.305 | 0.426 | (28) | 0.253 | 0.376 | (33) |
| CAD | 0.784 | 0.906 | (13) | 0.721 | 0.861 | (16) |
| CHF | 1.040 | 1.094 | (5) | 1.011 | 1.010 | 0 |
| CNY | 0.159 | 0.162 | (2) | 0.154 | 0.161 | (4) |
| EUR | 1.110 | 1.329 | (16) | 1.093 | 1.215 | (10) |
| GBP | 1.529 | 1.648 | (7) | 1.483 | 1.556 | (5) |
| JPY (100) | 0.826 | 0.947 | (13) | 0.831 | 0.836 | (1) |
| RUB (100) | 1.649 | 2.649 | (38) | 1.362 | 1.722 | (21) |

The following table provides a summary of the currency impact on key Group figures due to their conversion into $, the Group's reporting currency, of the financial data from entities reporting in non-US dollars. Constant currency (cc) calculations apply the exchange rates of the prior year to the current year financial data for entities reporting in non-US dollars.

**CURRENCY IMPACT ON KEY FIGURES**

| | Change in constant currencies % 2016 | Change in $ % 2016 | Percentage point currency impact 2016 | Change in constant currencies % 2015 | Change in $ % 2015 | Percentage point currency impact 2015 |
|---|---|---|---|---|---|---|
| Net sales from continuing operations | 0 | (2) | (2) | 5 | (5) | (10) |
| Operating income from continuing operations | (3) | (8) | (5) | (2) | (19) | (17) |
| Net income from continuing operations | 1 | (5) | (6) | (18) | (34) | (16) |
| Core operating income from continuing operations | (2) | (6) | (4) | 10 | (5) | (15) |
| Core net income from continuing operations | (3) | (6) | (3) | 9 | (5) | (14) |

For additional information on the effects of currency fluctuations, see "Note 29. Financial Instruments  Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

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**FREE CASH FLOW**

Novartis defines free cash flow as cash flow from operating activities and cash flow associated with the purchase or sale of property, plant and equipment, intangible, other non-current and financial assets, excluding marketable securities. Cash flows in connection with the acquisition or divestment of subsidiaries, associated companies and non-controlling interests in subsidiaries are not taken into account to determine free cash flow. For further information about the free cash flow measure, which is a non-IFRS measure, see "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Non-IFRS Measures as Defined by Novartis" above. The following is a summary of the free cash flow:

| | 2016 | 2015 | 2014 |
|---|---|---|---|
| | $ m | $ m | $ m |
| **Operating income from continuing operations** | **8,268** | **8,977** | **11,089** |
| Reversal of non-cash items | | | |
| Depreciation, amortization and impairments | 6,175 | 5,575 | 4,751 |
| Change in provisions and other non-current liabilities | 956 | 1,642 | 1,490 |
| Other | (264) | (96) | 122 |
| **Operating income adjusted for non-cash items** | **15,135** | **16,098** | **17,452** |
| Interest and other financial receipts | 942 | 1,180 | 1,067 |
| Interest and other financial payments | (878) | (669) | (692) |
| Taxes paid | (2,111) | (2,454) | (2,179) |
| Payments out of provisions and other net cash movements in non-current liabilities | (1,536) | (1,207) | (1,125) |
| Change in inventory and trade receivables less trade payables | (1,051) | (617) | (731) |
| Change in other net current assets and other operating cash flow items | 974 | (246) | 106 |
| **Cash flows from operating activities from continuing operations** | **11,475** | **12,085** | **13,898** |
| Purchase of property, plant & equipment | (1,862) | (2,367) | (2,624) |
| Proceeds from sales of property, plant & equipment | 161 | 237 | 60 |
| Purchase of intangible assets | (1,017) | (1,138) | (780) |
| Proceeds from sales of intangible assets | 847 | 621 | 246 |
| Purchase of financial assets | (247) | (264) | (239) |
| Proceeds from sales of financial assets | 247 | 166 | 431 |
| Purchase of other non-current assets | (149) | (82) | (60) |
| Proceeds from sales of other non-current assets | | 1 | 2 |
| **Free cash flow from continuing operations** | **9,455** | **9,259** | **10,934** |
| Free cash flow from discontinued operations | | (230) | (172) |
| **Free cash flow** | **9,455** | **9,029** | **10,762** |

***Financial year 2016***

In 2016, free cash flow from continuing operations amounted to $9.5 billion (+2% $) compared to $9.3 billion in 2015. The increase of $0.2 billion was mainly driven by lower net investments in property, plant and equipment.

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.

***Financial year 2015***

In 2015, free cash flow from continuing operations decreased by 15% to $9.3 billion compared to $10.9 billion in 2014. This decrease was primarily due to the negative currency impact on operations. The prior year also included higher proceeds from Novartis Venture Fund divestments and commercial settlements. Total free cash flow including the continuing and discontinued operations was $9.0 billion in 2015 compared to $10.8 billion in 2014.

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***Financial year 2014***

The free cash flow from continuing operations increased by $1.4 billion to $10.9 billion. This was primarily due to higher cash flows from operating activities, which mainly benefited from higher operating income adjusted for non-cash items, despite negative currency effects and increased hedging gains, partially offset by higher investments in intangible assets.

In 2014, free cash flow of the total Group increased by $0.8 billion to $10.8 billion compared to $9.9 billion in 2013.

**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | Dec 31, 2016 | Dec 31, 2015 | Change |
|---|---|---|---|
| | $ m | $ m | $ m |
| **Assets** | | | |
| Property, plant & equipment | 15,641 | 15,982 | (341) |
| Goodwill | 30,980 | 31,174 | (194) |
| Intangible assets other than goodwill | 31,340 | 34,217 | (2,877) |
| Financial and other non-current assets | 27,232 | 27,338 | (106) |
| **Total non-current assets** | **105,193** | **108,711** | **(3,518)** |
| Inventories | 6,255 | 6,226 | 29 |
| Trade receivables | 8,202 | 8,180 | 22 |
| Other current assets | 2,697 | 2,992 | (295) |
| Cash, marketable securities, commodities, time deposits and derivative financial instruments | 7,777 | 5,447 | 2,330 |
| **Total current assets** | **24,931** | **22,845** | **2,086** |
| **Total assets** | **130,124** | **131,556** | **(1,432)** |
| **Equity and liabilities** | | | |
| **Total equity** | **74,891** | **77,122** | **(2,231)** |
| Financial debts | 17,897 | 16,327 | 1,570 |
| Other non-current liabilities | 15,127 | 14,399 | 728 |
| **Total non-current liabilities** | **33,024** | **30,726** | **2,298** |
| Trade payables | 4,873 | 5,668 | (795) |
| Financial debts and derivatives | 5,905 | 5,604 | 301 |
| Other current liabilities | 11,431 | 12,436 | (1,005) |
| **Total current liabilities** | **22,209** | **23,708** | **(1,499)** |
| **Total liabilities** | **55,233** | **54,434** | **799** |
| **Total equity and liabilities** | **130,124** | **131,556** | **(1,432)** |

Total non-current assets of $105.2 billion at December 31, 2016 decreased by $3.5 billion compared to December 31, 2015.

Intangible assets other than goodwill decreased by $2.9 billion, mainly due to amortization and impairment charges totaling $4.5 billion, and unfavorable currency translation adjustments of $0.5 billion, partially offset by the impact of business combinations and additions totaling $2.1 billion. Property, plant and equipment decreased by 0.3 billion, mainly due to depreciation of $1.5 billion and unfavorable currency translation adjustments of $0.5 billion, partially offset by additions of $1.8 billion.

Goodwill decreased by $0.2 billion to $31.0 billion, mainly on account of currency translation adjustments.

Financial and other non-current assets decreased by $0.1 billion to $27.2 billion. This includes: investments in associated companies, which decreased by $1.0 billion to $14.3 billion, mainly on account of currency translation

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adjustments; deferred tax assets, which increased by $1.1 billion to $10.0 billion, mainly on intangible assets, inventories and pension obligations, and financial assets and other non-current assets which decreased by $0.2 billion to $2.9 billion.

Total current assets increased by $2.1 billion to $24.9 billion at December 31, 2016, mainly due to an increase in cash and cash equivalents, marketable securities, commodities and derivatives of $2.3 billion, partially offset by a decrease in other current assets of $0.3 billon. Inventories and trade receivables were broadly in line with the prior year.

Based on our current incurred loss provisioning approach, we consider that our doubtful debt provisions are adequate. However, we intend to continue to monitor the level of trade receivables in Greece, Italy, Portugal, Spain, Brazil, Russia and Saudi Arabia. Should there be a substantial deterioration in our economic exposure with respect to those countries, we may increase our level of provisions by moving to an expected loss provisioning approach or may change the terms of trade on which we operate.

The majority of the outstanding trade receivables from these closely monitored countries are due directly from local governments or from government-funded entities except for Russia, which are due from private entities. The gross trade receivables from these countries at December 31, 2016 amount to $1.5 billion (2015: $1.6 billion), of which $82 million are past due for more than one year (2015: $80 million) and for which provisions of $62 million have been recorded (2015: $56 million). At December 31, 2016, amounts past due for more than one year are not significant in any of these countries.

The following table provides an overview of our aging analysis of our trade receivables as of December 31, 2016 and 2015:

| | **2016** | **2015** |
|---|---|---|
| | **$ m** | **$ m** |
| Not overdue | 7,386 | 7,318 |
| Past due for not more than one month | 262 | 265 |
| Past due for more than one month but less than three months | 223 | 255 |
| Past due for more than three months but less than six months | 185 | 193 |
| Past due for more than six months but less than one year | 145 | 156 |
| Past due for more than one year | 163 | 135 |
| Provisions for doubtful trade receivables | (162) | (142) |
| **Total trade receivables, net** | **8,202** | **8,180** |

There is also a risk that certain countries could devalue their currency. Currency exposures are described in more detail, see " Effects of Currency Fluctuations" above.

Trade payables and other current liabilities decreased by $1.8 billion to $16.3 billion, compared to $18.1 billion at December 31, 2015, due to a decrease in other current liabilities of $1.0 billion and a decrease in trade payables of $0.8 billion.

Current income tax liabilities decreased by $0.1 billion to $1.6 billion. While there is some uncertainty about the final taxes to be assessed in our major countries, we believe that our estimated amounts for current income tax liabilities, including any amounts related to any uncertain tax positions, are appropriate based on currently known facts and circumstances.

In our key countries, Switzerland and the US, assessments have been agreed by the tax authorities up to 2014 in Switzerland and in the US up to 2012, with the exception of one open US position related to the 2007 and one for the 2010 tax filings.

Other non-current liabilities amounted to $15.1 billion at December 31, 2016, compared to $14.4 billion at December 31, 2015. The increase of $0.7 billion was primarily due to an increase in the pension liability of $0.5 billion, mainly resulting from a decrease in the actuarial discount rates used to calculate the present value of the benefit obligation and an increase in deferred tax liability of $0.3 billion.

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Other non-current liabilities include deferred tax liabilities of $6.7 billion, provisions and other non-current liabilities of $8.5 billion.

Novartis believes that its total provisions are adequate based upon currently available information. However, given the inherent difficulties in estimating liabilities in this area, Novartis may incur additional costs beyond the amounts provided. Management believes that such additional amounts, if any, would not be material to the Group's financial condition but could be material to the results of operations or cash flows in a given period.

The Group's equity decreased by $2.2 billion to $74.9 billion at December 31, 2016, compared to $77.1 billion at December 31, 2015. The decrease was mainly on account of unfavorable currency translation differences of $2.4 billion and net actuarial losses from defined benefit plans of $0.5 billion, partially offset by the Novartis share of other comprehensive income recognized by associated companies of $0.7 billion. The $6.5 billion dividend payment was offset by the net income of $6.7 billion.

The Group's liquidity amounted to $7.8 billion at December 31, 2016 compared to $5.4 billion at December 31, 2015, and net debt decreased to $16.0 billion at December 31, 2016 compared to $16.5 billion at December 31, 2015. The debt/equity ratio increased to 0.32:1 at December 31, 2016 compared to 0.28:1 at December 31, 2015.

**SUMMARY OF EQUITY MOVEMENTS ATTRIBUTABLE TO NOVARTIS AG SHAREHOLDERS**

| | Number of outstanding shares (in millions) | | | Issued share capital and reserves attributable to Novartis AG shareholders | | |
|---|---|---|---|---|---|---|
| | 2016 | 2015 | Change | 2016 | 2015 | Change |
| | | | | $ m | $ m | $ m |
| **Balance at beginning of year** | **2,373.9** | **2,398.6** | **(24.7)** | **77,046** | **70,766** | **6,280** |
| Shares acquired to be held in Group Treasury | | (9.6) | 9.6 | | (897) | 897 |
| Shares acquired to be canceled | (10.3) | (49.9) | 39.6 | (784) | (4,805) | 4,021 |
| Other share purchases | (2.6) | (4.1) | 1.5 | (208) | (417) | 209 |
| Exercise of options and employee transactions | 4.1 | 27.0 | (22.9) | 214 | 1,592 | (1,378) |
| Equity-based compensation | 9.0 | 11.9 | (2.9) | 664 | 815 | (151) |
| Decrease of treasury share repurchase obligation under a share buyback trading plan | | | | | 658 | (658) |
| Dividends | | | | (6,475) | (6,643) | 168 |
| Net income of the year attributable to shareholders of Novartis AG | | | | 6,712 | 17,783 | (11,071) |
| Impact of change in ownership of consolidated entities | | | | (7) | | (7) |
| Other comprehensive income attributable to shareholders of Novartis AG | | | | (2,330) | (1,806) | (524) |
| **Balance at end of year** | **2,374.1** | **2,373.9** | **0.2** | **74,832** | **77,046** | **(2,214)** |

During 2016, 13.1 million treasury shares were delivered as a result of options being exercised and physical share deliveries related to equity-based participation plans (2015: 38.9 million shares). Novartis repurchased 10.3 million shares on the SIX Swiss Exchange second trading line under the CHF 10 billion share buyback approved at the Annual General Meeting (AGM) in 2016, to offset the dilutive impact from equity-based participation plans (2015: 49.9 million shares under the $5 billion share buyback announced in November 2013, which was completed in November 2015). In addition, 2.6 million shares were acquired from employees, which were previously granted to them under the respective programs (2015: 4.1 million). No shares were repurchased on the SIX Swiss Exchange first trading line in 2016 (2015: 9.6 million). With these transactions, the total number of shares outstanding was increased by 0.2 million shares in 2016 (2015: reduction of 24.7 million shares).

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**Treasury shares**

At December 31, 2016, our holding of treasury shares amounted to 253.1 million shares or approximately 10% of the total number of issued shares. Approximately 135 million treasury shares are held in entities that limit their availability for use.

At December 31, 2015, our holding of treasury shares amounted to 303.1 million shares or approximately 11% of the total number of issued shares. Approximately 137 million treasury shares are held in entities that limit their availability for use.

At December 31, 2014, our holding of treasury shares amounted to 307.6 million shares or approximately 11% of the total number of issued shares. Approximately 153 million treasury shares are held in entities that limit their availability for use.

**Bonds**

In September 2016, two EUR bonds totaling EUR 1.75 billion were issued; a 7-year bond of EUR 1.25 billion with a coupon of 0.125% and a 12-year bond of EUR 0.5 billion with a coupon of 0.625%.

In June 2016, a EUR bond of EUR 1.5 billion with a coupon of 4.25% was repaid at maturity.

In February 2015, three Swiss franc bonds totaling CHF 1.375 billion were issued; a 10-year bond of CHF 0.5 billion with a coupon of 0.25%, a 14-year bond of CHF 0.55 billion with a coupon of 0.625% and a 20-year bond of CHF 0.325 billion with a coupon of 1.050%.

In November 2015, two US Dollar bonds totaling $3.0 billion were issued: a 10-year bond of $1.75 billion with a coupon of 3.0% and a 30-year bond of $1.25 billion with a coupon of 4.0%.

In April 2015, a 2.9% US Dollar bond of $2.0 billion was repaid at maturity. In June 2015, a 3.625% CHF bond of 0.8 billion was repaid at maturity.

In February 2014, two US Dollar bonds totaling $4.0 billion were issued; a 10-year bond of $2.15 billion with a coupon of 3.4% and a 30-year bond of $1.85 billion with a coupon of 4.4%. Further, a 4.125% US Dollar bond of $2.0 billion was repaid at maturity.

In October 2014, two EUR bonds totaling EUR1.2 billion were issued; a 7-year bond of EUR 0.6 billion with a coupon of 0.75% and a 12-year bond of EUR 0.6 billion with a coupon of 1.625%.

**Liquidity/Short-term Funding**

We continuously track our liquidity position and asset/liability profile. This involves modeling cash flow maturity profiles based on both historical experiences and contractual expectations to project our liquidity requirements. We seek to preserve prudent liquidity and funding capabilities.

We are not aware of significant demands to change our level of liquidity needed to support our normal business activities. We make use of various borrowing facilities provided by several financial institutions. We also successfully issued various bonds in previous years (including 2015 and 2016) and raised funds through our commercial paper programs. In addition, reverse repurchasing agreements are contracted and Novartis has entered into credit support agreements with various banks for derivative transactions. For details of the maturity profile of debt, currency and interest rate structure, see "Note 29. Financial Instruments  Additional Disclosures" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

**5.C Research & Development, Patents and Licenses**

Our R&D spending for continuing operations totaled $9.0 billion, $8.9 billion and $9.1 billion ($8.5 billion, $8.9 billion and $8.7 billion excluding impairments and amortization charges) for the years 2016, 2015 and 2014, respectively. Each of our divisions has its own R&D and patents policies. Our divisions have numerous products in various stages of development. For further information on these policies and these products in development, see "Item 4. Information on the Company  4.B Business Overview."

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As described in the "Risk Factors" section and elsewhere in this Form 20-F, our drug development efforts are subject to the risks and uncertainties inherent in any new drug development program. Due to the risks and uncertainties involved in progressing through pre-clinical development and clinical trials, and the time and cost involved in obtaining regulatory approvals, among other factors, we cannot reasonably estimate the timing, completion dates, and costs, or range of costs, of our drug development program, or of the development of any particular development compound, see "Item 3. Key Information  3.D Risk Factors." In addition, for a description of the research and development process for the development of new drugs and our other products, and the regulatory process for their approval, see "Item 4. Information on the Company  4.B Business Overview."

**5.D Trend Information**

Please see "  5.A Operating Results  Factors Affecting Results of Operations" and "Item 4. Information on the Company  4.B Business Overview" for trend information.

**5.E Off-Balance Sheet Arrangements**

We have no unconsolidated special purpose financing or partnership entities or other off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, that is material to investors, see also "Note 28. Commitments and Contingencies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017 and matters described in "Item 5.F Aggregate Contractual Obligations".

**5.F Tabular Disclosure of Contractual Obligations**

The following table summarizes the Group's contractual obligations and other commercial commitments, as well as the effect these obligations and commitments are expected to have on the Group's liquidity and cash flow in future periods:

| | | Payments due by period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 year | 2  3 years | 4  5 years | After 5 years |
| | $ m | $ m | $ m | $ m | $ m |
| Non-current financial debt, including current portion | 18,075 | 178 | 3,513 | 1,628 | 12,756 |
| Operating leases | 2,897 | 262 | 324 | 186 | 2,125 |
| Unfunded pensions and other post-employment benefit plans | 2,242 | 117 | 244 | 256 | 1,625 |
| Research & Development | | | | | |
| Potential milestone commitments | 4,175 | 385 | 854 | 2,283 | 653 |
| Purchase commitments | | | | | |
| Property, plant & equipment | 223 | 200 | 23 | | |
| **Total contractual cash obligations** | **27,612** | **1,142** | **4,958** | **4,353** | **17,159** |

The Group intends to fund the R&D and purchase commitments with internally generated resources.

On December 16, 2016 Novartis entered into an agreement to acquire Ziarco Goup Limited, a privately held company focused on the development of novel treatments in dermatology. The transaction closed on January 20, 2017. The total consideration of $420 million consists of an initial cash payment of $325 million before purchase price adjustments and preliminary present value of contingent consideration of $95 million.

On December 20, 2016 Novartis entered into a definitive agreement for the acquisition of Encore Vision, Inc, focused on the development of a novel treatment in presbyopia. The transaction closed on January 20, 2017. The total consideration of $465 million consists of an initial cash payment of $375 million before purchase price adjustments and preliminary present value of contingent consideration of $90 million. For further details on the

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above two transactions, see "Note 2. Significant Transactions" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

For other contingencies, see "Item 4. Information on the Company 4.D Property, Plants and Equipment Environmental Matters", "Item 8. Financial Information 8.A Consolidated Statements and Other Financial Information", and "Note 20. Provisions and other non-current Liabilities" and "Note 28 Commitments and Contigencies" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

## Item 6. Directors, Senior Management and Employees

### 6.A Directors and Senior Management

The information set forth under "Corporate governance Our Board Of Directors Board of Directors" on pages 94 to 97, and "Corporate Governance Our management Executive Committee" on pages 100 to 103, in each case of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

### 6.B Compensation

The information set forth under "Compensation Report" on pages 110 to 142 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

### 6.C Board Practices

The information set forth under "Corporate governance" on pages 76 to 93, on pages 98 to 99, and on pages 104 to 107, in each case of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

### 6.D Employees

The table below sets forth the breakdown of the total year-end number of our full time equivalent employees by main category of activity and geographic area for the past three years.

| For the year ended December 31, 2016 (full time equivalents) | Marketing & Sales | Production & Supply | Research & Development | NBS[1] | General & Administration | Total |
|---|---|---|---|---|---|---|
| USA | 6,615 | 6,836 | 7,363 | 1,517 | 706 | 23,037 |
| Canada and Latin America | 4,430 | 1,404 | 516 | 841 | 491 | 7,682 |
| Europe | 18,034 | 19,807 | 10,208 | 4,683 | 2,473 | 55,205 |
| Asia/Africa/Australasia | 17,825 | 7,029 | 3,504 | 3,007 | 1,104 | 32,469 |
| **Total** | **46,904** | **35,076** | **21,591** | **10,048** | **4,774** | **118,393** |

| For the year ended December 31, 2015 (full time equivalents) | Marketing & Sales | Production & Supply | Research & Development | NBS[1] | General & Administration | Total |
|---|---|---|---|---|---|---|
| USA | 6,027 | 6,735 | 7,684 | 1,583 | 653 | 22,682 |
| Canada and Latin America | 4,756 | 1,470 | 469 | 810 | 503 | 8,008 |
| Europe | 18,278 | 19,767 | 10,014 | 4,568 | 2,815 | 55,442 |
| Asia/Africa/Australasia | 18,611 | 6,819 | 3,413 | 2,515 | 1,210 | 32,568 |
| **Total** | **47,672** | **34,791** | **21,580** | **9,476** | **5,181** | **118,700** |

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| For the year ended December 31, 2014 (full time equivalents) | Marketing & Sales | Production & Supply | Research & Development | NBS[1] | General & Administration | Total |
|---|---|---|---|---|---|---|
| USA | 6,529 | 8,283 | 8,147 | 1,603 | 738 | 25,300 |
| Canada and Latin America | 5,309 | 2,435 | 515 | 326 | 1,001 | 9,586 |
| Europe | 20,884 | 23,997 | 11,052 | 3,909 | 3,225 | 63,067 |
| Asia/Africa/Australasia | 21,454 | 7,739 | 3,693 | 1,670 | 904 | 35,460 |
| **Total** | **54,176** | **42,454** | **23,407** | **7,508** | **5,868** | **133,413** |
| *Thereof Continuing Operations* | *48,638* | *36,106* | *21,181* | *7,508* | *4,376* | *117,809* |
| *Thereof Discontinued Operations* | *5,538* | *6,348* | *2,226* | | *1,492* | *15,604* |

(1) NBS relates to full time equivalent employees from our Novartis Business Services organizational unit.

As of December 31, 2015, the number of our full time equivalent employees decreased by approximately 15,000 compared to December 31, 2014, mainly due to the completion in 2015 of a series of transactions intended to transform our portfolio of businesses. For more information on these transactions, see the information set forth under "Note 2. Significant transactions" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017.

A significant number of our associates are represented by unions or works councils. We have not experienced any material work stoppages in recent years, and we consider our employee relations to be good.

**6.E Share Ownership**

The aggregate amount of our shares owned by our non-executive Directors and the members of our Executive Committee in 2016 (including persons closely linked to them) as of December 31, 2016 was 1,809,282 shares. This excludes certain unvested shares and other equity rights (such as Restricted Stock Units and Phantom Shares) because such unvested shares and equity rights do not represent shares held by these persons as of December 31, 2016.

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The aggregate amount of Novartis share and ADR options, including other information regarding the options, held by our non-executive Directors and the members of our Executive Committee in 2016, as of December 31, 2016 is set forth below:

| Title of Options | Amount of shares called for by the options | Exercise Price[1] | Purchase Price (if any) | Expiration Date | Total number of options held |
|---|---|---|---|---|---|
| Novas17 Options | 1 | 72.85 | 0 | February 3, 2017 | 0 |
| Novas18 Options | 1 | 64.05 | 0 | January 10, 2018 | 0 |
| Novas19 Options | 1 | 53.65 | 0 | January 18, 2019 | 0 |
| Novas20 Options | 1 | 55.85 | 0 | January 19, 2020 | 0 |
| Novas21 Options | 1 | 54.70 | 0 | January 19, 2021 | 141,396 |
| Novas22 Options | 1 | 54.20 | 0 | January 19, 2022 | 0 |
| Novas23 Options | 1 | 61.70 | 0 | January 17, 2023 | 0 |
| **Total Novartis Share Options** | | | | | **141,396** |
| Novartis ADR Options Cycle XI | 1 | $ 58.38 | 0 | February 3, 2017 | 0 |
| Novartis ADR Options Cycle XII | 1 | $ 57.96 | 0 | January 10, 2018 | 0 |
| Novartis ADR Options Cycle XIII | 1 | $ 46.42 | 0 | January 18, 2019 | 0 |
| Novartis ADR Options Cycle XIV | 1 | $ 53.70 | 0 | January 19, 2020 | 0 |
| Novartis ADR Options Cycle XV | 1 | $ 57.07 | 0 | January 19, 2021 | 0 |
| Novartis ADR Options Cycle XVI | 1 | $ 58.33 | 0 | January 19, 2022 | 0 |
| Novartis ADR Options Cycle XVII | 1 | $ 66.07 | 0 | January 17, 2023 | 0 |
| **Total Novartis ADR Options** | | | | | **0** |

(1) Exercise price indicated is per share, and denominated in Swiss francs for share options and US dollars for ADR options.

Information above for any former non-executive Directors and members of our Executive Committee who stepped down during 2016 is reported as of the date of their resignation.

Since 2014, we no longer grant any new share or ADR options to our non-executive Directors, the members of our Executive Committee and our associates under our equity based participation plans. For more information on the Novartis shares, share options and other equity based instruments owned by individual members of our Executive Committee and by our current non-executive Directors, see the information set forth under "Compensation Report Additional information Shares, ADRs, equity rights and share options owned by Executive Committee members" and "Compensation Report Additional information Shares, ADRs and other equity rights owned by Executive Committee members" on page 134, and under "Compensation Report 2016 Board compensation Shares, ADRs and share options owned by Board members" and "Compensation Report 2016 Board compensation Shares and ADRs owned by Board members" on page 140, in each case of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, which is incorporated by reference. For more information on our equity based participation plans, see the information set forth under "Note 26. Equity-based participation plans for associates" on pages 229 to 232 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, which is incorporated by reference.

## Item 7. Major Shareholders and Related Party Transactions

### 7.A Major Shareholders

Novartis shares are widely held. As of December 31, 2016, Novartis had approximately 171,000 shareholders listed in its share register, representing approximately 70.3% of issued shares. Based on the Novartis AG share register and excluding treasury shares, approximately 42.5% of the shares registered by name were held in Switzerland and approximately 23.9% were held in the US. Approximately 13.3% of the shares registered in the

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share register were held by individual investors, while approximately 86.7% were held by legal entities, nominees, fiduciaries and the ADS depositary.

Based on our share register, we believe that we are not directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons. There are no arrangements that may result in a change of control.

***2016***

According to the share register, as of December 31, 2016, excluding 4.5% of our share capital held as treasury shares by Novartis AG and its entities that restrict their availability for use, the following registered shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 2.6%; Emasan AG, with its registered office in Basel, Switzerland, holding 3.4%; and UBS Fund Management (Switzerland) AG, with its registered office in Basel, Switzerland, holding 2.1%;

Nominees: Chase Nominees Ltd., London, England (holding 8.5%); Nortrust Nominees, London, England (holding 3.9%); and The Bank of New York Mellon, New York, NY (holding 4.4%) through its nominees, Mellon Bank, Everett, MA (holding 1.8%) and The Bank of New York Mellon, Brussels, Belgium (holding 2.6%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 12%).

According to a disclosure notification filed with Novartis AG, Norges Bank (Central Bank of Norway), Oslo, Norway, held 2.02% of the share capital of Novartis AG as of December 31, 2016.

According to disclosure notifications filed with Novartis AG and the SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2016:

Capital Group Companies, Inc., Los Angeles, CA; and

BlackRock, Inc., New York, NY

As of December 31, 2016, no other shareholder was registered as owner of more than 2% of the registered share capital. Novartis has not entered into any agreement with any shareholder regarding the voting or holding of Novartis shares.

***2015***

According to the share register, as of December 31, 2015, excluding 6.2% of our share capital held as treasury shares by Novartis AG and its entities that restrict their availability for use, the following registered shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 2.6%; and Emasan AG, with its registered office in Basel, Switzerland, holding 3.3%;

Nominees: Chase Nominees Ltd., London, England (holding 8.8%) (Previously reported as JPMorgan Chase Bank, New York, NY but changed to its affiliate Chase Nominees Ltd., London, England, which is entered as nominee in our share register.); Nortrust Nominees, London, England (holding 3.2%); and The Bank of New York Mellon, New York, NY (holding 4.6%) through its nominees, Mellon Bank, Everett, MA (holding 1.7%) and The Bank of New York Mellon, Brussels, Belgium (holding 2.9%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 11.2%).

According to disclosure notifications filed with Novartis AG and the SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2015:

Capital Group Companies, Inc., Los Angeles, CA; and

BlackRock, Inc., New York, NY

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As of December 31, 2015, no other shareholder was registered as owner of more than 2% of the registered share capital. Novartis has not entered into any agreement with any shareholder regarding the voting or holding of Novartis shares.

***2014***

According to the share register, as of December 31, 2014, excluding 5.7% of our share capital held by Novartis AG, together with Novartis affiliates (excluding foundations), as treasury shares, the following registered shareholders (including nominees and the ADS depositary) held more than 2% of the total share capital of Novartis with the right to vote these shares:

Shareholders: Novartis Foundation for Employee Participation, with its registered office in Basel, Switzerland, holding 3.2%; and Emasan AG, with its registered office in Basel, Switzerland, holding 3.3%;

Nominees: JPMorgan Chase Bank, New York, NY (holding 9.1%); Nortrust Nominees, London, England (holding 3.2%); and The Bank of New York Mellon, New York, NY (holding 4.6%) through its nominees, Mellon Bank, Everett, MA (holding 2.6%) and The Bank of New York Mellon, Brussels, Belgium (holding 2.0%); and

ADS depositary: JPMorgan Chase Bank, New York, NY (holding 11.4%).

According to disclosure notifications filed with Novartis AG and the SIX Swiss Exchange, each of the following shareholders held between 3% and 5% of the share capital of Novartis AG as of December 31, 2014:

Capital Group Companies, Inc., Los Angeles, CA; and

BlackRock, Inc., New York, NY

As of December 31, 2014, no other shareholder was registered as owner of more than 2% of the registered share capital. Novartis has not entered into any agreement with any shareholder regarding the voting or holding of Novartis shares.

**7.B Related Party Transactions**

The information set forth under "Note 27. Transactions with related parties" on pages 233 to 234 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

**7.C Interests of Experts and Counsel**

Not applicable.

**Item 8. Financial Information**

**8.A Consolidated Statements and Other Financial Information**

See "Item 18. Financial Statements."

***Dividend policy***

Subject to the dividend policy described below, our Board of Directors expects to recommend the payment of a dividend in respect of each financial year. If approved by our shareholders at the relevant annual Shareholders' Meeting, the dividends will be payable shortly following such approval. Any shareholder who purchases our shares before the ex-dividend date and holds the shares until that date shall be deemed to be entitled to receive the dividends approved at that meeting. Dividends are reflected in our financial statements in the year in which they are approved by our shareholders.

Our dividend policy is to pay a growing annual dividend. This policy is subject to our financial conditions and outlook at the time, the results of our operations and other factors.

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The Board will propose a dividend of CHF 2.75 per share to the shareholders for approval at the Annual General Meeting to be held on February 28, 2017. Because we pay dividends in Swiss francs, exchange rate fluctuations will affect the US dollar amounts received by holders of ADRs. For a summary of dividends we paid in the past five years, see "Item 3. Key Information 3.A Selected Financial Data Cash Dividends per Share." See also "Item 3. Key Information 3.D Risk Factors 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."

***Disclosure pursuant to Section 219 of the Iran Threat Reduction & Syria Human Rights Act (ITRA)***

At Novartis, it is our mission to discover new ways to improve and extend people's lives, regardless of where they live. This includes the compliant sale of medicines and other healthcare products worldwide. To help us fulfill this mission, we have representative offices located in Iran.

As of October 18, 2010, a non-US affiliate within our Innovative Medicines Division entered into a non-binding Memorandum of Understanding (MoU) with the Ministry of Health and Medical Education of the Islamic Republic of Iran. Pursuant to the MoU, the Iranian Ministry of Health acknowledges certain benefits that may apply to sales of certain Innovative Medicines Division medicines by third-party distributors in Iran. These include fast-track registration, market exclusivity, end-user subsidies and exemptions from customs tariffs. Novartis receives no payments from the Iranian Ministry of Health under the MoU and the MoU creates no obligations on the part of either Novartis or the Iranian Ministry of Health.

In the second quarter of 2016, a non-US affiliate within our Innovative Medicines Division submitted a non-binding written proposal for potential collaboration related to local manufacturing, scientific and medical activities between the Iranian Ministry of Health and certain non-US affiliates within our Innovative Medicines and Sandoz Divisions. In the third quarter of 2016, a non-US affiliate within our Innovative Medicines Division submitted a draft of a proposed binding Memorandum of Understanding (MoU), based on the proposal submitted during the second quarter of 2016, to the Embassy of the Islamic Republic of Iran in Bern, Switzerland, to seek support for a meeting with representatives of the Iranian Ministry of Health to negotiate and finalize the MoU. A draft of the proposed binding MoU was submitted to the Iranian Ministry of Health and the Ministry of Foreign Affairs of Iran in the fourth quarter of 2016.

In 2016, non-US affiliates relating to our Innovative Medicines and Sandoz Divisions made payments to government entities in Iran related to exit fees and other transactions ordinarily incident to travel by doctors and other medical professionals resident in Iran to attend conferences or other events outside Iran.

From time to time, including in 2016, non-US affiliates relating to our Innovative Medicines and Sandoz Divisions enter into agreements with hospitals, research institutes, medical associations and universities in Iran to provide grants, sponsor congresses, seminars and symposia, and with doctors and other healthcare professionals for consulting services, including participation in advisory boards and investigator services for observational (non-interventional) studies. Some of these hospitals and research institutes are owned or controlled by the government of Iran, and some of these doctors and healthcare professionals are employed by hospitals that may be public or government-owned.

Because our Innovative Medicines and Sandoz Divisions have operations in Iran, including employees, they obtain services and have other dealings incidental to their activities in that country, including paying taxes and salaries either directly or indirectly through a service provider, and obtaining office rentals, insurance, electricity, water and telecommunications services, office and similar supplies and customs-related services from Iranian companies that may be owned or controlled by the government of Iran.

Some beneficiaries of payments made by non-US affiliates relating to our Innovative Medicines and Sandoz Divisions in the course of the operations described above maintain accounts at banks that are included on the list of Specially Designated Nationals (SDNs). Nonetheless, pursuant to Executive Order 13599, non-US persons are not subject to secondary sanctions for engaging in activities that involve persons included on the Executive Order 13599 List, given that the activities in question do not involve persons on the SDN List or conduct that remains sanctionable.

**8.B Significant Changes**

None.

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## Item 9. The Offer and Listing

### 9.A Offer and Listing Details

Our shares are listed in Switzerland on the SIX Swiss Exchange (SIX).

American Depositary Shares (ADSs), each representing one share, have been available in the US through an American Depositary Receipts (ADR) program since December 1996. This program was established pursuant to a Deposit Agreement which we entered into with JPMorgan Chase Bank N.A. as Depositary (Deposit Agreement). Our ADRs have been listed on the NYSE since May 2000, and are traded under the symbol "NVS."

The table below sets forth, for the periods indicated, the high and low closing sales prices for our shares traded in Switzerland and for ADRs traded in US. The data below regarding our shares reflects price and volume information for trades completed by members of the SIX during the day as well as for inter- dealer trades completed off the SIX and certain inter-dealer trades completed during trading on the previous business day.

The following share data was taken from SIX; the ADR data was taken from Bloomberg:

| | Shares | | ADRs | |
|---|---|---|---|---|
| | High CHF per share | Low CHF per share | High $ per ADR | Low $ per ADR |
| **Annual information for the past five years** | | | | |
| 2012 | 59.00 | 48.80 | 63.96 | 51.48 |
| 2013 | 73.65 | 58.70 | 80.39 | 63.70 |
| 2014 | 93.80 | 70.65 | 96.65 | 78.20 |
| 2015 | 102.30 | 82.20 | 106.12 | 83.96 |
| 2016 | 86.45 | 68.15 | 86.21 | 67.59 |
| **Quarterly information for the past two years** | | | | |
| **2016** | | | | |
| First Quarter | 86.45 | 69.55 | 86.21 | 71.11 |
| Second Quarter | 80.15 | 68.50 | 82.51 | 71.40 |
| Third Quarter | 82.50 | 76.10 | 83.51 | 78.27 |
| Fourth Quarter | 77.60 | 68.15 | 79.13 | 67.59 |
| **2015** | | | | |
| First Quarter | 99.70 | 84.30 | 103.00 | 91.67 |
| Second Quarter | 101.40 | 92.00 | 105.50 | 98.34 |
| Third Quarter | 102.30 | 87.35 | 106.12 | 89.52 |
| Fourth Quarter | 91.70 | 82.20 | 95.03 | 83.96 |
| **Monthly information for most recent six months** | | | | |
| August 2016 | 81.55 | 77.30 | 83.12 | 78.77 |
| September 2016 | 79.30 | 76.10 | 82.03 | 78.27 |
| October 2016 | 77.60 | 70.40 | 79.13 | 71.02 |
| November 2016 | 73.30 | 68.15 | 74.29 | 68.09 |
| December 2016 | 74.45 | 68.50 | 72.84 | 67.59 |
| January 2017 (through January 17, 2017) | 75.40 | 71.35 | 74.17 | 71.99 |

Fluctuations in the exchange rate between the Swiss franc and the US dollar will affect any comparisons of Swiss share prices and US ADR prices.

The average daily volumes of shares traded on the SIX (ON/OFF exchange) for the years 2016, 2015 and 2014 were 6,102,338, 5,870,874, and 4,963,517, respectively. These numbers are based on total annual turnover statistics supplied by the SIX via the Swiss Market Feed, which supplies such data to subscribers and to other

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information providers. The average daily volumes of ADRs traded in the US for the years 2016, 2015 and 2014 were 2,264,606, 1,787,735, and 1,504,087, respectively.

The Depositary has informed us that as of January 17, 2017, there were 314,369,587 ADRs outstanding, each representing one Novartis share (approximately 12% of total Novartis shares issued). On January 17, 2017, the closing sales price per share on the SIX was CHF 71.35 and $71.99 per ADR on the NYSE.

**9.B Plan of Distribution**

Not applicable.

**9.C Markets**

See "9.A Offer and Listing Details."

**9.D Selling Shareholders**

Not applicable.

**9.E Dilution**

Not applicable.

**9.F Expenses of the Issue**

Not applicable.

## Item 10. Additional Information

**10.A Share capital**

Not applicable.

**10.B Memorandum and Articles of Association**

The following is a summary of certain provisions of our Articles of Incorporation (Articles), our Regulations of the Board of Directors (Board Regulations) and of Swiss law, particularly, the Swiss Code of Obligations (Swiss CO). This is not a summary of all the significant provisions of the Articles, the Board Regulations or of Swiss law and does not purport to be complete. This description is qualified in its entirety by reference to the Articles and the Board Regulations, which are an exhibit to this Form 20-F, and to Swiss law.

At our 2015 Annual General Meeting held on February 27, 2015, our shareholders approved amendments to our Articles to align with the Swiss Ordinance against Excessive Compensation in Stock Exchange Listed Companies on Board and Executive Compensation (the "Ordinance"). Key aspects of these amendments included determining (i) the maximum number of allowable external mandates for members of our Board of Directors (Board) and Executive Committee (ECN), (ii) the principles concerning the tasks and responsibilities of our Compensation Committee, (iii) the details concerning the procedure for the new yearly binding separate shareholder votes on the aggregate compensation of our Board and ECN, and (iv) the principles of our compensation policy.

**10.B.1** ***Company Purpose***

Novartis AG is registered in the commercial register of the Canton of Basel-Stadt, Switzerland, under number CHE-103.867.266. Our business purpose, as stated in Article 2 of the Articles, is to hold interests in enterprises in the area of health care or nutrition. We may also hold interests in enterprises in the areas of

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biology, chemistry, physics, information technology or related areas. We may acquire, mortgage, liquidate or sell real estate and intellectual property rights in Switzerland or abroad. In pursuing our business purpose, we strive to create sustainable value.

**10.B.2** ***Directors***

(a) According to our Board Regulations, a member of our Board (Director) may not participate in deliberations or resolutions on matters which affect, or reasonably might affect, the Director's interests, or the interests of a person close to the Director. In addition, the Swiss CO sets forth that if, in connection with the conclusion of a contract, the Company is represented by the person with whom it is concluding the contract, such contract shall be in writing. Furthermore, the Swiss CO does require directors and members of senior management to safeguard the interests of the corporation and, in this connection, imposes a duty of care and a duty of loyalty on such individuals. This rule is generally interpreted to mean that directors and members of senior management are disqualified from participating in decisions which affect them personally.

(b) A Board resolution requires the affirmative majority of the votes cast. As with any Board resolution, Directors may not vote on their own compensation unless at least a majority of the Directors are present. Such votes are subject to the approval of the aggregate amounts of compensation of the Directors and the members of the ECN by a shareholders' resolution under the Ordinance.

(c) The Articles prohibit the granting of loans or credits to Directors.

(d) Directors who have turned seventy years of age at the date of the General Meeting of Shareholders may no longer be elected as members of the Board. The General Meeting of Shareholders may, under special circumstances, grant an exemption from this rule.

(e) Our Directors are not required to be shareholders under our Articles.

**10.B.3** ***Shareholder Rights***

Because Novartis AG has only one class of registered shares, the following information applies to all shareholders.

(a) The Swiss CO requires that at least 5% of our annual profit be retained as general reserves, so long as these reserves amount to less than 20% of our registered share capital. Swiss law and the Articles permit us to accrue additional reserves.

Under the Swiss CO, we may only pay dividends out of the balance sheet profit, out of reserves created for this purpose or out of free reserves. In any event, under the Swiss CO, while the Board may propose that a dividend be paid, we may only pay dividends upon shareholders' approval at a General Meeting of Shareholders. Our auditors must confirm that the dividend proposal of our Board conforms with the Swiss CO and the Articles. Our Board intends to propose a dividend once each year. See "Item 3. Key Information 3.A. Selected Financial Data Cash Dividends per Share" and "Item 8. Financial Information 8.A. Consolidated Financial Statements and Other Financial Information Dividend Policy."

Dividends are usually due and payable shortly after the shareholders have passed a resolution approving the payment. Dividends which have not been claimed within five years after the due date revert to us, and are allocated to our general reserves. For information about deduction of the withholding tax or other duties from dividend payments, see "Item 10. Additional Information 10.E Taxation."

(b) Each share is entitled to one vote at a General Meeting of Shareholders. Voting rights may only be exercised for shares registered with the right to vote on the Record Date. In order to do so, the shareholder must file a share registration form with us, setting forth the shareholder's name, address and citizenship (or, in the case of a legal entity, its registered office). If the shareholder has not timely filed the form, then the shareholder may not vote at, or participate in, General Meetings of Shareholders.

To vote its shares, the shareholder must also explicitly declare that it has acquired the shares in its own name and for its own account. If the shareholder refuses to make such a declaration, the shares may not be voted unless the Board recognizes such shareholder as a nominee.

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The Articles provide that no shareholder shall be registered with the right to vote shares comprising more than 2% of the registered share capital. The Board may, upon request, grant an exemption from this restriction. Considerations include whether the shareholder supports our goal of creating sustainable value and has a long-term investment horizon. Furthermore, the Articles provide that no nominee shall be registered with the right to vote shares comprising more than 0.5% of the registered share capital. The Board may, upon request, grant an exemption from this restriction if the nominee discloses the names, addresses and number of shares of the persons for whose account it holds more than 0.5% of the registered share capital. The same restrictions indirectly apply to holders of ADRs. We have in the past granted exemptions from the 2% rule for shareholders and the 0.5% rule for nominees. Under the Articles, the Board may delegate the power to grant such exemptions. The Board has delegated this power to the Chairman of the Board.

For purposes of the 2% rule for shareholders and the 0.5% rule for nominees, groups of companies and groups of shareholders acting in concert are considered to be one shareholder. These rules also apply to shares acquired or subscribed by the exercise of subscription, option or conversion rights.

After hearing the registered shareholder or nominee, the Board may cancel, with retroactive effect as of the date of registration, the registration of the shareholders if the registration was effected based on false information.

Registration restrictions in the Articles may only be removed upon a resolution carrying a two-thirds majority of the votes represented at a General Meeting of Shareholders.

Shareholders' resolutions generally require the approval of a majority of the votes present at a General Meeting of Shareholders. As a result, abstentions have the effect of votes against the resolution. Shareholder resolutions requiring a vote by such "absolute majority of the votes" include among others (1) amendments to the Articles; (2) elections of Directors, the Chairman, the Compensation Committee members, the independent proxy and the statutory auditors; (3) approval of the management report and the financial statements; (4) setting the annual dividend; (5) approval of the aggregate amounts of compensation of the Directors and the members of the Executive Committee; (6) decisions to discharge Directors and management from liability for matters disclosed to the General Meeting of Shareholders; and (7) the ordering of an independent investigation into specific matters proposed to the General Meeting of Shareholders.

According to the Articles and Swiss law, the following types of shareholders' resolutions require the approval of a "supermajority" of at least two-thirds of the votes present at a General Meeting of Shareholders: (1) an alteration of our corporate purpose; (2) the creation of shares with increased voting powers; (3) an implementation of restrictions on the transfer of registered shares and the removal of such restrictions; (4) an authorized or conditional increase of the share capital; (5) an increase of the share capital by conversion of equity, by contribution in kind, or for the purpose of an acquisition of property or the grant of special rights; (6) a restriction or an elimination of shareholders' preemptive rights; (7) a change of our domicile; (8) our dissolution; or (9) any amendment to the Articles which would create or eliminate a supermajority requirement.

Our shareholders have to annually elect all of the members of the Board, as well as the Chairman of the Board, the members of the Compensation Committee and the independent proxy. Cumulative voting of shares is not permitted under Swiss law.

At General Meetings of Shareholders, shareholders can be represented by proxy. However, a proxy must either be the shareholder's legal representative, another shareholder with the right to vote, or the independent proxy. Votes are taken either by a show of hands or by electronic voting, unless the General Meeting of Shareholders resolves to have a ballot or where a ballot is ordered by the chairman of the meeting.

American Depositary Shares (ADSs) each representing one Novartis share and evidenced by American Depositary Receipts (ADRs) are issued by our depositary JPMorgan Chase Bank, New York, and not by us. The ADR is vested with rights defined and enumerated in the Deposit Agreement (such as the rights to vote, to receive a dividend and to receive a share of Novartis in exchange for a certain number of ADRs). The enumeration of rights, including any limitations on those rights in the Deposit Agreement, is final. There are no other rights given to the ADR holders. Only the ADS depositary, holding our shares underlying the ADRs, is registered as shareholder in our share register. An ADR is not a Novartis share and an ADR holder is not a Novartis shareholder.

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The Deposit Agreement between our depositary, the ADR holder and us has granted certain indirect rights to vote to the ADR holders. ADR holders may not attend Novartis General Meetings in person. ADR holders exercise their voting rights by instructing JPMorgan Chase Bank, our depositary, to exercise the voting rights attached to the registered shares underlying the ADRs. Each ADR represents one Novartis share. JPMorgan Chase Bank exercises the voting rights for registered shares underlying ADRs for which no voting instructions have been given by providing a discretionary proxy to an uninstructed independent designee pursuant to paragraph 13 of the form of ADR. Such designee has to be a shareholder of Novartis. The same voting restrictions apply to ADR holders as to those holding Novartis shares (*i.e.*, the right to vote up to 2% of the Novartis registered share capital unless otherwise granted an exemption by the Board and disclosure requirement for nominees).

(c) Shareholders have the right to allocate the profit shown on our balance sheet by vote taken at the General Meeting of Shareholders, subject to the legal requirements described in "Item 10.B.3(a) Shareholder Rights".

(d) Under the Swiss CO, any surplus arising out of a liquidation of our Company (*i.e.*, after the settlement of all claims of all creditors) would be distributed to the shareholders in proportion to the paid-in nominal value of their shares.

(e) The Swiss CO limits a corporation's ability to hold or repurchase its own shares. We and our subsidiaries may only repurchase shares if we have freely disposable equity, in the amount necessary for this purpose, available. The aggregate nominal value of all Novartis shares held by us and our subsidiaries may not exceed 10% of our registered share capital. However, it is accepted that a corporation may repurchase its own shares beyond the statutory limit of 10%, if the repurchased shares are clearly earmarked for cancellation. In addition, we are required to create a special reserve on our balance sheet in the amount of the purchase price of the acquired shares. Repurchased shares held by us or our subsidiaries do not carry any rights to vote at a General Meeting of Shareholders, but are entitled to the economic benefits generally connected with the shares. It should be noted that the definition of what constitutes subsidiaries, and therefore, treasury shares, for purposes of the above described reserves requirement and voting restrictions differs from the definition included in the consolidated financial statements. The definition in the consolidated financial statements requires consolidation for financial reporting purposes of special purpose entities, irrespective of their legal structure, in instances where we have the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

Under the Swiss CO, we may not cancel treasury shares without the approval of a capital reduction by our shareholders.

(f) Not applicable.

(g) Since all of our issued and outstanding shares have been fully paid in, we can make no further capital calls on our shareholders.

(h) See Items "10.B.3(b) Shareholder Rights" and "10.B.7 Change in Control".

**10.B.4** ***Changes To Shareholder Rights***

Under the Swiss CO, we may not issue new shares without the prior approval of a capital increase by our shareholders. If a capital increase is approved, then our shareholders would generally have certain preemptive rights to obtain newly issued shares in an amount proportional to the nominal value of the shares they already hold. These preemptive rights could be modified in certain limited circumstances with the approval of a resolution adopted at a General Meeting of Shareholders by a supermajority of votes. In addition, we may not create shares with increased voting powers or place restrictions on the transfer of registered shares without the approval of a resolution adopted at a General Meeting of Shareholders by a supermajority of votes. In addition, see Item 10.B.3(b) with regard to the Board's ability to cancel the registration of shares under limited circumstances.

**10.B.5** ***Shareholder Meetings***

Under the Swiss CO and the Articles, we must hold an annual ordinary General Meeting of Shareholders within six months after the end of our financial year. General Meetings of Shareholders may be convened by the

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Board or, if necessary, by the statutory auditors. The Board is further required to convene an extraordinary General Meeting of Shareholders if so resolved by a General Meeting of Shareholders, or if so requested by shareholders holding an aggregate of at least 10% of the registered shares, specifying the items for the agenda and their proposals. Shareholders holding shares with a nominal value of at least CHF 1,000,000 (*i.e.*, 2,000,000 Novartis shares) have the right to request that a specific proposal be put on the agenda and voted upon at the next General Meeting of Shareholders. A General Meeting of Shareholders is convened by publishing a notice in the official Swiss Commercial Gazette (*Schweizerisches Handelsamtsblatt*) at least 20 days prior to such meeting. Shareholders may also be informed by mail. There is no provision in the Swiss CO or our Articles requiring a quorum for the holding of a General Meeting of Shareholders. In addition, see "Item 10.B.3(b) Shareholder Rights" regarding conditions for exercising a shareholder's right to vote at a General Meeting of Shareholders.

**10.B.6** ***Limitations***

There are no limitations under the Swiss CO or our Articles on the right of non-Swiss residents or nationals to own or vote shares other than the restrictions applicable to all shareholders. But see "Item 10.B.3(b) Shareholder Rights" regarding conditions for exercising an ADR holder's right to vote at a shareholder meeting.

**10.B.7** ***Change in Control***

The Articles and the Board Regulations contain no provision that would have an effect of delaying, deferring or preventing a change in control of Novartis and that would operate only with respect to a merger, acquisition or corporate restructuring involving us or any of our subsidiaries.

According to the Swiss Merger Act, shareholders may pass a resolution to merge with another corporation at any time. Such a resolution would require the consent of at least two-thirds of all votes present at the necessary General Meeting of Shareholders.

Under the Swiss Financial Market Infrastructure Act, shareholders and groups of shareholders acting in concert who acquire more than $33^{1}/_{3}\%$ of our shares would be under an obligation to make an offer to acquire all remaining Novartis shares. Novartis has neither an opting-out from the mandatory takeover offer obligation nor an opting-up of the threshold for mandatory takeover offers in its Articles.

**10.B.8** ***Disclosure of Shareholdings***

Under the Swiss Financial Market Infrastructure Act, holders of our voting shares acting alone or acting in concert with others are required to notify us and the SIX Swiss Exchange of the level of their holdings whenever such holdings reach or exceed, or in some cases, fall short of, certain thresholds 3%, 5%, 10%, 15%, 20%, 25%, $33^{1}/_{3}\%$, 50% and $66^{2}/_{3}\%$ of our registered share capital. Following receipt of such notification we are required to inform the public by publishing the information via the electronic publication platform operated by the competent Disclosure Office.

An additional disclosure obligation exists under the Swiss CO which requires us to disclose, once a year in the notes to the financial statements published in our annual report, the identity of all of our shareholders (or related groups of shareholders) who have been granted exemption entitling them to vote more than 2% of our registered share capital, as described in "Item 10.B.3(b) Shareholder Rights".

**10.B.9** ***Differences in the Law***

See the references to Swiss law throughout this "Item 10.B Memorandum and Articles of Association".

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**10.B.10** ***Changes in Capital***

The requirements of the Articles regarding changes in capital are not more stringent than the requirements of Swiss law.

**10.C Material contracts**

***Transactions with GSK***

On April 22, 2014, we entered into agreements with GSK for the Consumer Healthcare Joint Venture, the Vaccines Sale and the Oncology Acquisition (each as defined below and, together, the "Transactions"). The Transactions were completed on March 2, 2015.

*Consumer Healthcare Joint Venture with GSK*

On April 22, 2014 (and as amended, and amended and restated, from time to time), we entered into a Contribution Agreement with GSK under which GSK contributed its consumer healthcare business (the "GSK Consumer Healthcare Business") and we contributed our OTC Division, with certain limited exceptions which include the over-the-counter business of our Sandoz Division, into a newly-created joint venture which operates under the GSK Consumer Healthcare name (the "Consumer Healthcare Joint Venture"). In consideration for those contributions, GSK owns 63.5% of the issued share capital of the Consumer Healthcare Joint Venture and we own 36.5% of the issued share capital of the Consumer Healthcare Joint Venture.

On March 2, 2015 (and as amended from time to time), the Shareholders' Agreement which governs the operation of the Consumer Healthcare Joint Venture became operative concurrently with the creation of the Consumer Healthcare Joint Venture. Under the Shareholders' Agreement, GSK has the right to appoint seven directors to the board of the Consumer Healthcare Joint Venture and we have the right to appoint four directors to the board of the Consumer Healthcare Joint Venture. The Shareholders' Agreement also contains certain minority shareholder protections, including the right to exit the Consumer Healthcare Joint Venture via a put option exercisable in certain windows in the period from the third to the twentieth anniversary of the creation of the Consumer Healthcare Joint Venture.

*Sale of Vaccines Business (Excluding our Influenza Vaccines Business) to GSK*

On April 22, 2014 (and as amended, and amended and restated, from time to time), we entered into a Share and Business Sale Agreement with GSK under which we sold our Vaccines Division (with certain limited exceptions, and except for our influenza vaccines business) to GSK (the "Vaccines Sale") for up to $7.1 billion, consisting of $5.25 billion upfront and up to $1.8 billion in milestones, of which we have received $450 million as of December 31, 2016, plus royalties. We completed the Vaccines Sale on March 2, 2015.

*Oncology Acquisition from GSK*

On April 22, 2014 (and as amended, and amended and restated, from time to time), we entered into a Sale and Purchase Agreement with GSK under which we acquired GSK oncology products and certain related assets (the "Oncology Acquisition"). GSK has also granted us a right of first negotiation over the co-development and commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines, for a period of twelve and one half years from closing. We completed the Oncology Acquisition on March 2, 2015. Novartis paid an aggregate cash consideration of $16 billion for the Oncology Acquisition.

***Sale of Influenza Vaccines Business to CSL***

On October 26, 2014 (and as amended, and amended and restated, from time to time), we entered into a Share and Business Sale Agreement with CSL under which we divested our Vaccines Division's influenza vaccines business to CSL for $275 million. This transaction was completed effective July 31, 2015.

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***Sale of Animal Health Division to Lilly***

On April 22, 2014 (and as amended from time to time), we entered into a Stock and Asset Purchase Agreement with Lilly. Under this agreement, Lilly agreed to purchase our Animal Health Division (with certain limited exceptions) for approximately $5.4 billion. This transaction was completed on January 1, 2015.

**10.D Exchange controls**

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to Novartis, the export or import of capital, including any foreign exchange controls, or that generally affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold Novartis' shares.

**10.E Taxation**

The taxation discussion set forth below is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects relevant to the ownership or disposition of our shares or ADRs. The statements of US and Swiss tax laws set forth below are based on the laws and regulations in force as of the date of this 20-F, including the current Convention Between the US and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, entered into force on December 19, 1997 (the "Treaty"), and the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations, rulings, judicial decisions and administrative pronouncements, and may be subject to any changes in US and Swiss law, and in any double taxation convention or treaty between the US and Switzerland occurring after that date, which changes may have retroactive effect.

**Swiss Taxation**

***Swiss Residents***

*Withholding Tax on Dividends and Distributions.* Dividends which we pay and similar cash or in-kind distributions which we may make to a holder of shares or ADRs (including distributions of liquidation proceeds in excess of the nominal value, stock dividends and, under certain circumstances, proceeds from repurchases of shares by us in excess of the nominal value) are generally subject to a Swiss federal withholding tax (the "Withholding Tax") at a current rate of 35%. Under certain circumstances distributions out of capital contribution reserves made by shareholders after December 31, 1996 are exempt from Withholding Tax. We are required to withhold this Withholding Tax from the gross distribution and to pay the Withholding Tax to the Swiss Federal Tax Administration. The Withholding Tax is refundable in full to Swiss residents who are the beneficial owners of the taxable distribution at the time it is resolved and duly report the gross distribution received on their personal tax return or in their financial statements for tax purposes, as the case may be.

*Income Tax on Dividends.* A Swiss resident who receives dividends and similar distributions (including stock dividends and liquidation surplus) on shares or ADRs is required to include such amounts in the shareholder's personal income tax return. However, distributions out of qualified capital contribution reserves are not subject to income tax. A corporate shareholder may claim substantial relief from taxation of dividends and similar distributions received if the shares held represent a fair market value of at least CHF 1 million.

*Capital Gains Tax upon Disposal of Shares.* Under current Swiss tax law, the gain realized on shares held by a Swiss resident who holds shares or ADRs as part of his private property is generally not subject to any federal, cantonal or municipal income taxation on gains realized on the sale or other disposal of shares or ADRs. However, gains realized upon a repurchase of shares by us may be characterized as taxable dividend income if certain conditions are met. Book gains realized on shares or ADRs held by a Swiss corporate entity or by a Swiss resident individual as part of the shareholder's business property are, in general, included in the taxable income of such person. However, the Federal Law on the Direct Federal Tax of December 14, 1990 and several cantonal laws on direct cantonal taxes provide for exceptions for Swiss corporate entities holding more than 10% of our voting stock for more than one year.

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***Residents of Other Countries***

Recipients of dividends and similar distributions on our shares who are neither residents of Switzerland for tax purposes nor holding shares as part of a business conducted through a permanent establishment situated in Switzerland ("Non-resident Holders") are not subject to Swiss income taxes in respect of such distributions. Moreover, gains realized by such recipients upon the disposal of shares are not subject to Swiss income taxes.

Non-resident Holders of shares are, however, subject to the Withholding Tax on dividends and similar distributions mentioned above and under certain circumstances to the Stamp Duty described below. Such Non-resident Holders may be entitled to a partial refund of the Withholding Tax if the country in which they reside has entered into a bilateral treaty for the avoidance of double taxation with Switzerland. Non-resident Holders should be aware that the procedures for claiming treaty refunds (and the time frame required for obtaining a refund) may differ from country to country. Non-resident Holders should consult their own tax advisors regarding receipt, ownership, purchase, sale or other dispositions of shares or ADRs and the procedures for claiming a refund of the Withholding Tax.

As of January 1, 2017, Switzerland has entered into bilateral treaties for the avoidance of double taxation with respect to income taxes with the following countries, whereby a part of the above-mentioned Withholding Tax may be refunded (subject to the limitations set forth in such treaties):

| | | | |
|---|---|---|---|
| Albania | Finland | Latvia | Russia |
| Algeria | France | Liechtenstein | Serbia |
| Argentina | Germany | Lithuania | Singapore |
| Armenia | Georgia | Luxembourg | Slovak Republic |
| Australia | Ghana | Macedonia | Slovenia |
| Austria | Greece | Malaysia | South Africa |
| Azerbaijan | Hong Kong | Malta | Spain |
| Bahrain | Hungary | Mexico | Sri Lanka |
| Bangladesh | Iceland | Moldova | Sweden |
| Belarus | India | Mongolia | Taiwan |
| Belgium | Indonesia | Montenegro | Tajikistan |
| Bulgaria | Iran | Morocco | Thailand |
| Canada | Israel | Netherlands | Trinidad and Tobago |
| Chile | Italy | New Zealand | Tunisia |
| China | Ivory Coast | Norway | Turkey |
| Colombia | Republic of Ireland | Oman | Turkmenistan |
| Croatia | Jamaica | Pakistan | Ukraine |
| Cyprus | Japan | Peru | United Arab Emirates |
| Czech Republic | Kazakhstan | Philippines | United Kingdom |
| Denmark | Republic of Korea | Poland | United States of America |
| Ecuador | (South Korea) | Portugal | Uruguay |
| Egypt | Kuwait | Qatar | Uzbekistan |
| Estonia | Kyrgyzstan | Romania | Venezuela |
| | | | Vietnam |

The tax treaty with Bahrain is not applicable to the healthcare industry. Tax treaty negotiations are under way, or have been conducted, with Bosnia and Herzegovina, Brazil, Costa Rica, Libya, North Korea, Saudi Arabia, Senegal, Syria, and Zimbabwe. Tax treaty negotiations between Switzerland and some of the countries listed in the immediately preceding sentence have been ongoing for an extended period of time, and we are not certain when or if such negotiations will be completed, and when or if the corresponding treaties will come into effect.

A Non-resident Holder of shares or ADRs will not be liable for any Swiss taxes other than the Withholding Tax described above and, if the transfer occurs through or with a Swiss bank or other Swiss securities dealer, the Stamp Duty described below. If, however, the shares or ADRs of Non-resident Holders can be attributed to a permanent establishment or a fixed place of business maintained by such person within Switzerland during the relevant tax year, the shares or ADRs may be subject to Swiss income taxes in respect of income and gains

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realized on the shares or ADRs and such person may qualify for a full refund of the Withholding Tax based on Swiss tax law.

*Residents of the US.* A Non-resident Holder who is a resident of the US for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 15% of the dividend, provided that such holder (i) qualifies for benefits under the Treaty, (ii) holds, directly and indirectly, less than 10% of our voting stock, and (iii) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares or ADRs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 15% Treaty rate. A Non-resident Holder who is a resident of the US for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 5% of the dividend, provided that such holder (i) is a company, (ii) qualifies for benefits under the Treaty, (iii) holds directly at least 10% of our voting stock, and (iv) does not conduct business through a permanent establishment or fixed place of business in Switzerland to which the shares or ADRs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 5% Treaty rate. Claims for refunds must be filed on Swiss Tax Form 82 (82C for corporations; 82I for individuals; 82E for other entities), which may be obtained from any Swiss Consulate General in the US or from the Federal Tax Administration of Switzerland at the address below, together with an instruction form. Four copies of the form must be duly completed, signed before a notary public of the US, and sent to the Federal Tax Administration of Switzerland, Eigerstrasse 65, CH-3003 Berne, Switzerland. The form must be accompanied by suitable evidence of deduction of Swiss tax withheld at source, such as certificates of deduction, signed bank vouchers or credit slips. The form may be filed on or after July 1 or January 1 following the date the dividend was payable, but no later than December 31 of the third year following the calendar year in which the dividend became payable. For US resident holders of ADRs, JPMorgan Chase Bank, N.A., as Depositary, will comply with these Swiss procedures on behalf of the holders, and will remit the net amount to the holders.

*Stamp Duty upon Transfer of Securities.* The sale of shares, whether by Swiss residents or Non-resident Holders, may be subject to federal securities transfer Stamp Duty of 0.15%, calculated on the sale proceeds, if the sale occurs through or with a Swiss bank or other Swiss securities dealer, as defined in the Swiss Federal Stamp Duty Act. The Stamp Duty has to be paid by the securities dealer and may be charged to the parties in a taxable transaction who are not securities dealers. Stamp Duty may also be due if a sale of shares occurs with or through a non-Swiss bank or securities dealer, provided (i) such bank or dealer is a member of the SIX, and (ii) the sale takes place on the SIX. In addition to this Stamp Duty, the sale of shares by or through a member of the SIX may be subject to a minor stock exchange levy.

**US Federal Income Taxation**

The following is a general discussion of the material US federal income tax consequences of the ownership and disposition of our shares or ADRs that may be relevant to you if you are a US Holder (as defined below). Because this discussion does not consider any specific circumstances of any particular holder of our shares or ADRs, persons who are subject to US taxation are strongly urged to consult their own tax advisers as to the overall US federal, state and local tax consequences, as well as to the overall Swiss and other foreign tax consequences, of the ownership and disposition of our shares or ADRs. In particular, additional or different rules may apply to US expatriates, banks and other financial institutions, regulated investment companies, traders in securities who elect to apply a mark-to-market method of accounting, dealers in securities or currencies, tax-exempt entities, insurance companies, broker-dealers, investors liable for alternative minimum tax, investors that hold shares or ADRs as part of a straddle, hedging or conversion transaction, holders whose functional currency is not the US dollar, partnerships or other pass through entities, persons who acquired our shares pursuant to the exercise of employee stock options or otherwise as compensation and persons who hold directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares. This discussion generally applies only to US Holders who hold the shares or ADRs as a capital asset (generally, for investment purposes), and whose functional currency is the US dollar. Investors are urged to consult their own tax advisors concerning whether they are eligible for benefits under the Treaty.

For purposes of this discussion, a "US Holder" is a beneficial owner of our shares or ADRs who is (i) an individual who is a citizen or resident of the US for US federal income tax purposes, (ii) a corporation (or other entity taxable as a corporation for US federal income tax purposes) created or organized in or under the laws of the US or a state thereof or the District of Columbia, (iii) an estate the income of which is subject to US federal income taxation regardless of its source, or (iv) a trust (i) subject to the primary supervision of a US court and the

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control of one or more US persons or (ii) that has a valid election in place to be treated as a US person. If a partnership (or other entity treated as a partnership for US federal income tax purposes) holds shares or ADRs, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. Partners in a partnership that holds shares or ADRs are urged to consult their own tax advisor regarding the specific tax consequences of the owning and disposing of such shares or ADRs by the partnership.

For US federal income tax purposes, a US Holder of ADRs generally will be treated as the beneficial owner of our shares represented by the ADRs. However, see the discussion below under " Dividends" regarding certain statements made by the US Treasury concerning depositary arrangements.

This discussion assumes that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms.

*Dividends.* US Holders will be required to include in gross income, as an item of ordinary income, the full amount (including the amount of any Withholding Tax) of a dividend paid with respect to our shares or ADRs at the time that such dividend is received by the US Holder, in the case of shares, or by the Depository, in the case of ADRs. For this purpose, a "dividend" will include any distribution paid by us with respect to our shares or ADRs (other than certain pro rata distributions of our capital stock) paid out of our current or accumulated earnings and profits, as determined under US federal income tax principles. To the extent the amount of a distribution by us exceeds our current and accumulated earnings and profits, such excess will first be treated as a tax-free return of capital to the extent of a US Holder's tax basis in the shares or ADRs (with a corresponding reduction in such tax basis), and thereafter will be treated as capital gain, which will be long-term capital gain if the US Holder held our shares or ADRs for more than one year. Under the Code, dividend payments by us on the shares or ADRs are not eligible for the dividends received deduction generally allowed to corporate shareholders.

Dividend income in respect of our shares or ADRs will constitute income from sources outside the US for US foreign tax credit purposes. Subject to the limitations and conditions provided in the Code, US Holders generally may claim as a credit against their US federal income tax liability, any Withholding Tax withheld from a dividend. The rules governing the foreign tax credit are complex. Each US Holder is urged to consult its own tax advisor concerning whether, and to what extent, a foreign tax credit will be available with respect to dividends received from us. Alternatively, a US Holder may claim the Withholding Tax as a deduction for the taxable year within which the Withholding Tax is paid or accrued, provided a deduction is claimed for all of the foreign income taxes the US Holder pays or accrues in the particular year. A deduction does not reduce US tax on a dollar-for-dollar basis like a tax credit. The deduction, however, is not subject to the limitations applicable to foreign tax credits.

The US Treasury has expressed concern that parties to whom ADRs are released may be taking actions inconsistent with the claiming of foreign tax credits for US Holders of ADRs. Accordingly, the summary above of the creditability of the Withholding Tax could be affected by future actions that may be taken by the US Treasury.

In general, a US Holder will be required to determine the amount of any dividend paid in Swiss francs, including the amount of any Withholding Tax imposed thereon, by translating the Swiss francs into US dollars at the spot rate on the date the dividend is actually or constructively received by a US Holder, in the case of shares, or by the Depositary, in the case of ADRs, regardless of whether the Swiss francs are in fact converted into US dollars. If a US Holder converts the Swiss francs so received into US dollars on the date of receipt, the US Holder generally should not recognize foreign currency gain or loss on such conversion. If a US Holder does not convert the Swiss francs so received into US dollars on the date of receipt, the US Holder will have a tax basis in the Swiss francs equal to the US dollar value on such date. Any foreign currency gain or loss that a US Holder recognizes on a subsequent conversion or other disposition of the Swiss francs generally will be treated as US source ordinary income or loss.

For a non-corporate US Holder, the US dollar amount of any dividends paid that constitute qualified dividend income generally will be taxable at a maximum rate of 15%. However, for tax year 2016, the top rate is 20% for taxpayers with incomes exceeding $415,050 ($466,950 for joint filing taxpayers) provided that the US Holder meets certain holding period and other requirements. In addition, the dividends could be subject to a 3.8% net investment income tax. This tax is applied against the lesser of the US Holder's net investment income or modified adjusted gross income over $200,000 ($250,000 for joint filing taxpayers). We currently believe that dividends paid with respect to our shares and ADRs will constitute qualified dividend income for US federal

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income tax purposes. However, the US Treasury and the US Internal Revenue Service ("IRS") have announced their intention to promulgate rules pursuant to which US Holders of shares and ADRs, among others, will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. US Holders of shares or ADRs are urged to consult their own tax advisors regarding the availability to them of the reduced dividend rate in light of their own particular situation and the computations of their foreign tax credit limitation with respect to any qualified dividends paid to them, as applicable.

*Sale or Other Taxable Disposition.* Upon a sale or other taxable disposition of shares or ADRs, US Holders generally will recognize capital gain or loss in an amount equal to the difference between the US dollar value of the amount realized on the disposition and the US Holder's tax basis (determined in US dollars) in the shares or ADRs. This capital gain or loss generally will be US source gain or loss and will be treated as long-term capital gain or loss if the holding period in the shares or ADRs exceeds one year. In the case of certain US Holders (including individuals), any long term capital gain generally will be subject to US federal income tax at preferential rates, which rates are subject to a maximum of 20% for taxpayers with incomes exceeding $415,050 ($466,950 for joint filing taxpayers) for gains recognized after January 1, 2016. In addition, the gains could be subject to a 3.8% investment income tax. This tax is applied against the lesser of the US Holder's net investment income or modified adjusted gross income over $200,000 ($250,000 for joint filing taxpayers). The deductibility of capital losses is subject to significant limitations under the Code. Deposits or withdrawals of our shares by US Holders in exchanges for ADRs will not result in the realization of gain or loss for US federal income tax purposes.

*US Information Reporting and Backup Withholding.* Dividend payments with respect to shares or ADRs and proceeds from the sale, exchange or other disposition of shares or ADRs received in the United States or through US-related financial intermediaries, may be subject to information reporting to the IRS and possible US backup withholding. Certain exempt recipients (such as corporations) are not subject to these information reporting and backup withholding requirements. Backup withholding will not apply to a US Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. Any US Holders required to establish their exempt status generally must provide a properly-executed IRS Form W-9 (Request for Taxpayer Identification Number and Certification). Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a US Holder's US federal income tax liability, and a US Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

**10.F Dividends and paying agents**

Not applicable.

**10.G Statement by experts**

Not applicable.

**10.H Documents on display**

Any statement in this Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Form 20-F the contract or document is deemed to modify the description contained in this Form 20-F. You must review the exhibits themselves for a complete description of the contract or document.

You may review a copy of our filings with the SEC, as well as other information furnished to the SEC, including exhibits and schedules filed with it, at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the SEC maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the SEC. These SEC filings are also available to the public from commercial document retrieval services.

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We are required to file or furnish reports and other information with the SEC under the Securities Exchange Act of 1934 and regulations under that act. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the form and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short swing profit recovery provisions contained in Section 16 of the Exchange Act.

**10.I Subsidiary Information**

Not applicable.

**Item 11. Quantitative and Qualitative Disclosures about Market Risk**

The major financial risks facing the Group are managed centrally by Group Treasury. We have a written Treasury Directive and have implemented a strict segregation of front office and back office controls. The Group does regular reconciliations of its positions with its counterparties. In addition the Treasury function is included in management's internal control assessment.

For information about the effects of currency fluctuations and how we manage currency risk, see "Item 5. Operating and Financial Review and Prospects  Item 5.B Liquidity and Capital Resources".

The information set forth under "Note 29. Financial instruments  additional disclosures" on pages 236 to 244 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

**Item 12. Description of Securities Other than Equity Securities**

**12.A Debt Securities**

Not applicable.

**12.B Warrants and Rights**

Not applicable.

**12.C Other Securities**

Not applicable.

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**12.D American Depositary Shares**

***Fees Payable By ADR Holders***

According to our Deposit Agreement with the ADS depositary, JPMorgan Chase Bank (JPMorgan), holders of our ADRs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth below:

| Category | Depositary actions | Associated Fee |
|---|---|---|
| Depositing or substituting underlying shares | Acceptance of shares surrendered, and issuance of ADRs in exchange, including surrenders and issuances in respect of:<br>Share distributions<br>Stock split<br>Rights<br>Merger<br>Exchange of shares or any other transaction or event or other distribution affecting the ADSs or the deposited shares | $5.00 for each 100 ADSs (or portion thereof) evidenced by the new ADRs delivered |
| Withdrawing underlying shares | Acceptance of ADRs surrendered for withdrawal of deposited shares | $5.00 for each 100 ADSs (or portion thereof) evidenced by the ADRs surrendered |
| Selling or exercising rights | Distribution or sale of shares, the fee being in an amount equal to the fee for the execution and delivery of ADRs which would have been charged as a result of the deposit of such shares | $5.00 for each 100 ADSs (or portion thereof) |
| Transferring, splitting or grouping receipts | Transfers, combining or grouping of depositary receipts | $1.50 per ADR |
| Expenses of the depositary | Expenses incurred on behalf of holders in connection with<br>compliance with foreign exchange control regulations or any law or regulation relating to foreign investment<br>the depositary's or its custodian's compliance with applicable law, rule or regulation.<br>stock transfer or other taxes and other governmental charges<br>cable, telex and facsimile transmission and delivery<br>expenses of the depositary in connection with the conversion of foreign currency into US dollars (which are paid out of such foreign currency)<br>any other charge payable by any of the depositary or its agents | Expenses payable at the sole discretion of the Depositary by billing Holders or by deducting charges from one or more cash dividends or other cash distributions. |
| Advance tax relief | Tax relief/reclamation process for qualified holders. | A depositary service charge of $0.0075 per ADS |

***Fees Payable By The Depositary To The Issuer***

Pursuant to an agreement effective as of May 11, 2012, JPMorgan, as depositary, has agreed to reimburse Novartis $1.0 million per quarter, a total of $4.0 million per contract year, for expenses incurred directly related to our ADR program (the "Program") which were incurred during the contract year, including Program-related legal fees, expenses related to investor relations in the US, US investor presentations, ADR-related financial advertising and public relations, reasonable accountants' fees in relation to our Form 20-F, maintenance and broker reimbursement expenses. Because our expenses related to these categories exceed $4.0 million (see, for example, the amount of our accountants' fees set forth under "Corporate Governance  Our Independent External Auditors  Audit and Additional Fees" in the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017), the $4.0 million cannot be deemed to have reimbursed us for any particular one or more of these expenses.

JPMorgan has further agreed not to seek reimbursement of up to $50,000 of out-of-pocket expenses incurred annually in providing such administrative services.

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## PART II

### Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

### Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

None.

### Item 15. Controls and Procedures

(a) Novartis AG's chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective.

(b) Report of Novartis Management on Internal Control Over Financial Reporting: The Board of Directors and management of the Group are responsible for establishing and maintaining adequate internal control over financial reporting. The Group's internal control system was designed to provide reasonable assurance to the Group's management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of its published consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Group management assessed the effectiveness of the Group's internal control over financial reporting as of December 31, 2016. In making this assessment, it used the criteria established in *Internal Control  Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our assessment, management concluded that, as of December 31, 2016, the Group's internal control over financial reporting is effective based on those criteria.

PricewaterhouseCoopers AG, Switzerland, an independent registered public accounting firm, has issued an unqualified opinion on the effectiveness of the Group's internal control over financial reporting which is included in this Form 20-F under "Item 18. Financial Statements  Report of Independent Registered Public Accounting Firm."

(c) See the report of PwC, an independent registered public accounting firm, included under "Item 18. Financial Statements  Report of Independent Registered Public Accounting Firm."

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 16A. Audit Committee Financial Expert

Our Audit and Compliance Committee has determined that Srikant Datar and Elizabeth Doherty each possess specific accounting and financial management expertise and that each is an Audit Committee Financial Expert as defined by the US Securities and Exchange Commission (SEC). The Board of Directors has also determined that Srikant Datar and Elizabeth Doherty are each "independent" in accordance with the applicable requirements of Rule 10A-3 of the US Securities Exchange Act of 1934, and that other members of the Audit and Compliance Committee have sufficient experience and ability in finance and compliance matters to enable them to adequately discharge their responsibilities.

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**Item 16B. Code of Ethics**

In addition to our Code of Conduct, which is applicable to all of our associates, we have adopted a Code of Ethical Conduct that imposes additional obligations on our principal executive officer, principal financial officer, principal accounting officer, and persons performing similar functions. This document is accessible on our Internet website at

https://www.novartis.com/investors/company-overview/corporate-governance

**Item 16C. Principal Accountant Fees and Services**

The information set forth under "Corporate governance  Our independent external auditors" on pages 104 to 105 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

Not Applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

| 2016 | Total Number of Shares Purchased (a)[1] | Average Price Paid per Share in $ (b) | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)[2] | Maximum Approximate Value of Shares that may yet be purchased under the Plans or Programs in CHF (d) (CHF millions) | Maximum Approximate Value of Shares that may yet be purchased under the Plans or Programs in $[3] ($ millions) |
|---|---|---|---|---|---|
| Jan. 1  31 | 1,437,086 | 76.49 | | | |
| Feb. 1  29 | 155,477 | 75.52 | | 10,000 | 10,042 |
| Mar. 1  31 | 3,139,398 | 73.30 | 2,970,000 | 9,789 | 10,149 |
| Apr. 1  30 | 104,523 | 75.37 | | 9,789 | 10,161 |
| May 1  31 | 76,328 | 77.03 | | 9,789 | 9,869 |
| Jun. 1  30 | 82,179 | 79.75 | | 9,789 | 9,980 |
| Jul. 1  31 | 155,309 | 82.12 | | 9,789 | 10,006 |
| Aug. 1  31 | 2,866,371 | 80.11 | 2,800,000 | 9,570 | 9,734 |
| Sep. 1  30 | 3,125,617 | 79.69 | 3,000,000 | 9,338 | 9,666 |
| Oct. 1  31 | 78,047 | 77.53 | | 9,338 | 9,448 |
| Nov. 1  30 | 1,597,761 | 68.84 | 1,500,000 | 9,233 | 9,092 |
| Dec. 1  31 | 99,652 | 69.81 | | 9,233 | 9,030 |
| **Total** | **12,917,748** | **76.37** | **10,270,000** | | |

(1) Column (a) shows shares we purchased as part of our seventh share repurchase program plus the following types of share purchases outside of our publicly announced repurchase program: (1) shares which we purchased on the open market; and (2) shares which we purchased from Swiss employees who had obtained the shares through a Novartis Employee Ownership Plan. See the information set forth under "Note 26. Equity-based participation

plans for associates" on pages 229 to 232 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, which is incorporated by reference.

(2) Column (c) shows shares purchased as part of our seventh share repurchase program which was approved by the shareholders February 23, 2016 for an amount of up to CHF 10.0 billion. See the information set forth under "Corporate governance  Our shares

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and our shareholders  Our shares  Share repurchase programs" on page 80 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, which is incorporated by reference.

(3) Column (e) shows the Swiss franc amount from column (d) converted into US dollars as of the month-end, using the Swiss franc/US dollar exchange rate at the applicable month-end.

**Item 16F. Change in Registrant's Certifying Accountant**

Not applicable.

**Item 16G. Corporate Governance**

The information set forth under "Corporate governance  Our corporate governance framework" on page 105 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

**Item 16H. Mine Safety Disclosure**

Not applicable.

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## PART III

### Item 17. Financial Statements

See response to "Item 18. Financial Statements."

### Item 18. Financial Statements

The information set forth under the headings

"Consolidated income statements" on page 178;

"Consolidated statements of comprehensive income" on page 179;

"Consolidated statements of changes in equity" on page 180;

"Consolidated balance sheets" on page 181;

"Consolidated cash flow statements" on page 182; and

"Notes to the Novartis Group consolidated financial statements" on pages 183 to 247,

in each case of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017, is incorporated by reference.

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**Report of Independent Registered Public Accounting Firm**

**To the Shareholders and Board of Directors of Novartis AG, Basel**

In our opinion, the accompanying consolidated balance sheets and the related consolidated income statements, consolidated statements of comprehensive income, consolidated statements of changes in equity, consolidated cash flow statements and notes (as referred to in item 18 of this Form 20-F) present fairly, in all material respects, the financial position of Novartis AG and its consolidated subsidiaries (Group or Company) at December 31, 2016 and December 31, 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016 in conformity with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control  Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

The Novartis' Board of Directors and management of the Group are responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the "Report of Novartis Management on Internal Control Over Financial Reporting" in item 15(b) of this Form 20-F. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that

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controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers AG

| /s/ BRUNO ROSSI | /s/ STEPHEN JOHNSON |
|---|---|
| Bruno Rossi<br>*Audit expert*<br>*Auditor in charge* | Stephen Johnson<br>*Global relationship partner* |

Basel, January 24, 2017

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**Item 19. Exhibits**

1.1 Articles of Incorporation of Novartis AG, as amended February 23, 2016 (English translation).

1.2 Regulations of the Board and Committee Charters of Novartis AG, as amended in relevant part January 1, 2014, March 1, 2015, and November 1, 2015 (incorporated by reference to Exhibit 1.2 to the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016).

2.1 Amended and Restated Deposit Agreement, dated as of May 11, 2000 among Novartis AG, JPMorgan Chase Bank (fka Morgan Guaranty Trust Company of New York), as depositary, and all holders from time to time of ADRs issued thereunder (incorporated by reference to Exhibit (a)(1) to Post-Effective Amendment No. 1 to Novartis AG's registration statement on Form F-6 (File No. 333-11758) as filed with the SEC on September 8, 2000).

2.2 Amendment No. 1 to the Amended and Restated Deposit Agreement (incorporated by reference to Exhibit (a)(2) to Post-Effective Amendment No. 1 to Novartis AG's registration statement on Form F-6 (File No. 333-11758) as filed with the SEC on September 8, 2000).

2.3 Amendment No. 2 to the Amended and Restated Deposit Agreement (incorporated by reference to Exhibit (a)(3) to Novartis AG's registration statement on Form F-6 (File No. 333-13446) as filed with the SEC on May 7, 2001).

2.4 Restricted Issuance Agreement dated as of January 11, 2002 among Novartis AG, J.P. Morgan Chase Bank, as depositary, and all holders from time to time of ADRs representing ADSs issued thereunder (incorporated by reference to Exhibit 4 to the Registration Statement on Form F-3, File No. 333-81862, as filed with the SEC on January 31, 2002).

2.5 Letter Agreement dated December 14, 2007 between Novartis AG and JPMorgan Chase Bank, as depositary (incorporated by reference to Exhibit 2.4 to the Form 20-F for the year ended December 31, 2007 as filed with the SEC on January 28, 2008).

2.6 Form of American Depositary Receipt (incorporated by reference to Exhibit (a)(7) to the Registration Statement on Form F-6, File No. 333-198623, as filed with the SEC on September 8, 2014).

2.7 The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.

4.1 Contribution Agreement relating to the Consumer Healthcare Joint Venture made on April 22, 2014, as amended and restated on May 29, 2014 and March 1, 2015, between Novartis AG, GlaxoSmithKline plc and GlaxoSmithKline Consumer Healthcare Holdings Limited (formerly known as Leo Constellation Limited). Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.2 of the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016.)

4.2 Share and Business Sale Agreement relating to the Vaccines Group made on April 22, 2014, as amended and restated on May 29, 2014, as further amended on October 9, 2014, and as further amended and restated on March 1, 2015, between Novartis AG and GlaxoSmithKline plc. Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.3 of the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016.)

4.3 Sale and Purchase Agreement in relation to the Oncology Business made on April 22, 2014, as amended and restated on May 29, 2014, November 21, 2014 and March 1, 2015, between GlaxoSmithKline plc and Novartis AG. Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.4 of the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016.)

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| 4.4 | Stock and Asset Purchase Agreement made on April 22, 2014, as amended on December 17, 2014, between Novartis AG and Eli Lilly and Company. Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.6 of the Form 20-F for the year ended December 31, 2014, as filed with the SEC on January 27, 2015.) |
| 4.5 | Share and Business Sale Agreement relating to the Flu Group made on October 26, 2014, as amended and restated on July 31, 2015, between Novartis AG and CSL Limited. Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.7 of the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016.) |
| 4.6 | Shareholders' Agreement relating to GlaxoSmithKline Consumer Healthcare Holdings Limited made on March 2, 2015, between GlaxoSmithKline Consumer Healthcare Holdings Limited, GlaxoSmithKline plc, Setfirst Limited, Novartis AG, Novartis Holding AG and Novartis Finance Corporation. Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and filed separately with the SEC. (Incorporated by reference to Exhibit 4.8 of the Form 20-F for the year ended December 31, 2015, as filed with the SEC on January 27, 2016.) |
| 6.1 | Our earnings per share calculation is incorporated by reference to "Note 7. Earnings per share" on page 202 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017. |
| 8.1 | A list of all of our principal Group subsidiaries and associated companies is incorporated by reference to "Note 32. Principal Group subsidiaries and associated companies" on pages 246 to 247 of the "Excerpts from Novartis Annual Report 2016" furnished to the SEC on Form 6-K on January 25, 2017. |
| 12.1 | Certification of Joseph Jimenez, Chief Executive Officer of Novartis AG, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 12.2 | Certification of Harry Kirsch, Chief Financial Officer of Novartis AG, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 13.1 | Certification of Joseph Jimenez, Chief Executive Officer of Novartis AG, pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 13.2 | Certification of Harry Kirsch, Chief Financial Officer of Novartis AG, pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 15.1 | Consent of Independent Registered Public Accounting Firm, PricewaterhouseCoopers AG, to the incorporation by reference of the audit report contained in this Form 20-F into Novartis AG's Registration Statements on Form S-8 filed on October 1, 2004 (File No. 333-119475), on Form S-8 filed on September 5, 2006 (File No. 333-137112), on Form S-8 filed on October 29, 2009 (File No. 333-162727), on Form S-8 filed on January 18, 2011 (File No. 333-171739), on Form S-8 filed on April 8, 2011 (File No. 333-173382), on Form S-8 filed on September 12, 2014 (File No. 333-198706), and on Form F-3 filed on September 18, 2015 (File No. 333-207004). |
| 15.2 | Excerpts from Novartis Annual Report 2016 (incorporated by reference to Exhibit 99.1 to Form 6-K as furnished to the SEC on January 25, 2017). |

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**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

NOVARTIS AG

By: /s/ HARRY KIRSCH

Name: Harry Kirsch
Title: *Chief Financial Officer, Novartis Group*

By: /s/ FELIX R. EHRAT

Name: Felix R. Ehrat
Title: *General Counsel, Novartis Group*

Date: January 25, 2017