NOVARTIS AG
Form 20-F
January 26, 2010

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**As filed with the Securities and Exchange Commission on January 26, 2010**

# 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, 2009

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)*

Thomas Werlen
Group General Counsel
Novartis AG
CH-4056 Basel
Switzerland
011-41-61-324-2745
thomas.werlen@novartis.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

**None**

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

**None**

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

**2,274,353,351 shares**

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

**Yes ý No o**

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

**Yes o No ý**

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

**Yes ý No o**

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

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

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

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

**Item 17 o Item 18 o**

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

**Yes o No ý**

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## INTRODUCTION

Novartis AG and its consolidated affiliates (Novartis or the Group) publish consolidated financial statements expressed in US dollars. Our consolidated financial statements found in Item 18 of this annual report on Form 20-F (Form 20-F) are those for the year ended December 31, 2009 and are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

## USE OF CERTAIN TERMS

In this Form 20-F, references to "US dollars," "$" or "USD" are to the lawful currency of the United States of America, and references to "CHF" are to Swiss francs; references to the "United States" or to "US" are to the United States of America, references to the European Union (EU) are to the European Union and its 27 member states and references to "Americas" are to North, Central (including the Caribbean) and South America, unless the context otherwise requires; references to "ADS" or "ADSs" are to Novartis American Depositary Shares; references to "associates" are to employees of our affiliates; references to the "FDA" are to the US Food and Drug Administration, and references to "EMEA" are to the European Medicines Agency, an agency of the EU. All product names appearing in italics are trademarks owned by or licensed to Group companies. Product names identified by a "®" or a " " are trademarks that are not owned by or licensed to Group companies. You will find the words "we," "our," "us" and similar words or phrases in this Form 20-F. We use those words to comply with the requirement of the US Securities and Exchange Commission to use "plain English" in public documents like this Form 20-F. For the sake of clarification, each Group company is legally separate from all other Group companies and manages its business independently through its respective board of directors or other top local management body. No Group company operates the business of another Group company nor is any Group company the agent of any other Group company. Each executive identified in this Form 20-F reports directly to other executives of the Group company which employs the executive, or to that Group company's board of directors.

## FORWARD LOOKING STATEMENTS

This Form 20-F contains certain "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which can be identified by terminology such as "planned," "expected," "will," "potential," "pipeline," "outlook," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products, or potential future sales or earnings of the Novartis Group or any of its divisions or business units; or regarding the potential acquisition and merger with Alcon; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for existing products in any market, or that such products will achieve any particular revenue levels. Nor can there be any guarantee that the Novartis Group, or any of its divisions or business units, will achieve any particular financial results. Neither can there be any guarantee that the proposed acquisition and merger with Alcon will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Novartis will be able to realize any of the potential synergies, strategic benefits or opportunities as a result of the proposed acquisition. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results,

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including additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection; uncertainties regarding actual or potential legal proceedings, including, among others, product liability litigation, litigation regarding sales and marketing practices, government investigations and intellectual property disputes; competition in general; government, industry, and general public pricing and other political pressures; uncertainties regarding the after-effects of the recent global financial and economic crisis; uncertainties regarding future global exchange rates and uncertainties regarding future demand for our products; uncertainties involved in the development of new pharmaceutical products; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet. Some of these factors are discussed in more detail herein, including under "Item 3. Key Information  3.D. Risk factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects." Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Form 20-F as anticipated, believed, estimated or expected. We provide the information in this 20-F as of the date of its filing. We do not intend, and do not assume any obligation, to update any information or forward looking statements set out in this Form 20-F as a result of new information, future events or otherwise.

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## PART I

### Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

### Item 2. Offer Statistics and Expected Timetable

Not applicable.

### Item 3. Key Information

#### 3.A Selected Financial Data

The selected financial information set out below has been extracted from our consolidated financial statements prepared in accordance with IFRS as issued by the IASB. Our consolidated financial statements for the years ended December 31, 2009, 2008 and 2007 are included in "Item 18. Financial Statements" in this Form 20-F.

The results of our Medical Nutrition and Gerber Business Units are shown as discontinued operations for all periods presented, following their divestment in 2007. See "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Factors Affecting Comparability of Year-on-Year Results of Operations" and "Item 18. Financial Statements note 2" for more detailed discussion.

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

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| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2007 | 2006 | 2005 |
| | ($ millions, except per share information) | | | | |
| **INCOME STATEMENT DATA** | | | | | |
| **Net sales from continuing operations** | **44,267** | **41,459** | **38,072** | **34,393** | **29,446** |
| **Operating income from continuing operations** | **9,982** | **8,964** | **6,781** | **7,642** | **6,507** |
| Income from associated companies | 293 | 441 | 412 | 264 | 193 |
| Financial income | 198 | 384 | 531 | 354 | 461 |
| Interest expense | (551) | (290) | (237) | (266) | (294) |
| **Income before taxes from continuing operations** | **9,922** | **9,499** | **7,487** | **7,994** | **6,867** |
| Taxes | 1,468 | (1,336) | (947) | (1,169) | (986) |
| **Net income from continuing operations** | 8,454 | 8,163 | 6,540 | 6,825 | 5,881 |
| Net income from discontinued operations | | 70 | 5,428 | 377 | 260 |
| **Group net income** | **8,454** | **8,233** | **11,968** | **7,202** | **6,141** |
| Attributable to: | | | | | |
| Shareholders of Novartis AG | 8,400 | 8,195 | 11,946 | 7,175 | 6,130 |
| Non-controlling interests | 54 | 38 | 22 | 27 | 11 |
| Operating income from discontinued operations (including divestment gains) | | 70 | 6,152 | 532 | 398 |
| **Basic earnings per share ($):** | | | | | |
| Continuing operations | 3.70 | 3.59 | 2.81 | 2.90 | 2.52 |
| Discontinued operations | | 0.03 | 2.34 | 0.16 | 0.11 |
| Total | 3.70 | 3.62 | 5.15 | 3.06 | 2.63 |
| **Diluted earnings per share ($):** | | | | | |
| Continuing operations | 3.69 | 3.56 | 2.80 | 2.88 | 2.51 |
| Discontinued operations | | 0.03 | 2.33 | 0.16 | 0.11 |
| Total | 3.69 | 3.59 | 5.13 | 3.04 | 2.62 |
| Cash dividends[1] | 3,941 | 3,345 | 2,598 | 2,049 | 2,107 |
| Cash dividends per share in CHF[2] | 2.10 | 2.00 | 1.60 | 1.35 | 1.15 |
| **Operating income from continuing operations earnings per share ($):** | | | | | |
| Basic | 4.40 | 3.96 | 2.93 | 3.26 | 2.79 |
| Diluted | 4.38 | 3.92 | 2.91 | 3.24 | 2.78 |

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

(2) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2009 will be proposed to the Annual General Meeting on February 26, 2010 for approval.

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| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2007 | 2006 | 2005 |
| | | | ($ millions) | | |
| **BALANCE SHEET DATA** | | | | | |
| Cash, cash equivalents and marketable securities & derivative financial instruments | 17,449 | 6,117 | 13,201 | 7,955 | 10,933 |
| Inventories | 5,830 | 5,792 | 5,455 | 4,498 | 3,725 |
| Other current assets | 10,412 | 8,972 | 8,774 | 8,215 | 6,785 |
| Non-current assets | 61,814 | 57,418 | 48,022 | 46,604 | 36,289 |
| Assets held for sale related to discontinued operations | | | | 736 | |
| **Total assets** | **95,505** | **78,299** | **75,452** | **68,008** | **57,732** |
| Trade accounts payable | 4,012 | 3,395 | 3,018 | 2,487 | 1,961 |
| Other current liabilities | 15,458 | 13,109 | 13,623 | 13,540 | 13,367 |
| Non-current liabilities | 18,573 | 11,358 | 9,415 | 10,480 | 9,240 |
| Liabilities related to discontinued operations | | | | 207 | |
| **Total liabilities** | **38,043** | **27,862** | **26,056** | **26,714** | **24,568** |
| Issued share capital and reserves attributable to shareholders of Novartis AG | 57,387 | 50,288 | 49,223 | 41,111 | 32,990 |
| Non-controlling interests | 75 | 149 | 173 | 183 | 174 |
| **Total equity** | **57,462** | **50,437** | **49,396** | **41,294** | **33,164** |
| **Total liabilities and equity** | **95,505** | **78,299** | **75,452** | **68,008** | **57,732** |
| Net assets | 57,462 | 50,437 | 49,396 | 41,294 | 33,164 |
| Outstanding share capital | 825 | 820 | 815 | 850 | 848 |
| Total outstanding shares (millions) | 2,274 | 2,265 | 2,264 | 2,348 | 2,336 |

**Cash Dividends per Share**

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

| Year Earned | Month and Year Paid | Total Dividend per share (CHF) | Total Dividend per share in $ ($) |
|---|---|---|---|
| 2005 | February 2006 | 1.15 | 0.89 |
| 2006 | March 2007 | 1.35 | 1.09 |
| 2007 | February 2008 | 1.60 | 1.53 |
| 2008 | February 2009 | 2.00 | 1.72 |
| 2009[1] | February 2010 | 2.10 | 2.04[2] |

(1) Dividend to be proposed at the Annual General Meeting on February 26, 2010 and to be distributed March 5, 2010.

(2) Translated into US dollars at the 2009 Reuters Market System period end rate of $0.97 to the Swiss franc. This translation is an example only, and should not be construed as a representation that the Swiss franc amount represents, or has been or could be converted into US dollars at that or any other rate.

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**Exchange Rates**

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Reuters Market System. The exchange rate in effect on January 19, 2010, as found on Reuters Market System, was CHF 1.00 = $0.97.

| **Year ended December 31, ($ per CHF)** | **Period End** | **Average[1]** | **Low** | **High** |
|---|---|---|---|---|
| 2005 | 0.76 | 0.80 | 0.75 | 0.88 |
| 2006 | 0.82 | 0.80 | 0.76 | 0.84 |
| 2007 | 0.88 | 0.83 | 0.80 | 0.91 |
| 2008 | 0.94 | 0.93 | 0.82 | 1.02 |
| 2009 | 0.97 | 0.92 | 0.84 | 1.00 |
| **Month end,** | | | | |
| August 2009 | | | 0.92 | 0.95 |
| September 2009 | | | 0.94 | 0.98 |
| October 2009 | | | 0.96 | 0.99 |
| November 2009 | | | 0.97 | 1.00 |
| December 2009 | | | 0.95 | 1.00 |
| January 2010[2] | | | 0.96 | 0.98 |

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

(2) Through January 19, 2010.

**3.B Capitalization and Indebtedness**

Not applicable.

**3.C Reasons for the offer and use of proceeds**

Not applicable.

**3.D Risk Factors**

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

**Risks Facing Our Business**

***Our Pharmaceuticals Division faces and will continue to face important patent expirations and aggressive generic competition.***

Our Pharmaceuticals Division's products are generally protected by patent rights, which are intended to provide us with exclusive rights to market the patented products. However, those patent rights are of

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varying strengths and durations. Loss of market exclusivity for one or more important products which we will face in the near future will have a material adverse effect on our results of operations.

The introduction of a generic version of a branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at sharply lower prices. Such competition can result from the regular expiration of the term of the patent. Such competition can also result from the entry of generic versions of another medicine in the same therapeutic class as one of our drugs, or in another competing therapeutic class. In addition, generic manufacturers are taking an increasingly aggressive approach to challenging patents, conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement, before final resolution of legal proceedings.

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

Some of our best-selling products are expected to face significant competition in the coming years due to the end of market exclusivity resulting from the expiry of patent protection.

The patent on valsartan, the active ingredient of our top-selling drug, *Diovan/Co-Diovan/Diovan HCT* (high blood pressure), expires in the major countries of the EU during 2011, in the US in September 2012, and in Japan in 2013. Our sales may also be impacted in 2010 when a competitor product, Cozaar®, is expected to become the first branded medicine in the same therapeutic class as *Diovan* to lose market exclusivity. In addition, the active ingredient valsartan is also used in the single-pill combination therapies *Exforge/Exforge HCT* (high blood pressure). While there is an expectation that market exclusivities for *Exforge/Exforge HCT* will remain in the EU and Japan due to regulatory exclusivities, there is a risk that the product may face generic competition in the US in September 2012.

The patent on *Femara* (cancer) will expire in 2011 in the US and in major European markets, while generic versions have already been launched in some smaller European markets.

Patents protecting the *Sandostatin LAR* (acromegaly) formulation, the long-acting version of this drug that represents a majority of our *Sandostatin* sales, expire in July 2010 in major markets outside the US, and in 2014 and beyond in the US.

Some of our products are also the subject of ongoing patent litigation. In particular, zoledronic acid, the active ingredient in *Zometa* (cancer), as well as in *Reclast/Aclasta* (osteoporosis), is currently the subject of US patent litigation, with the possibility of an "at risk launch" of a generic version of *Zometa* by one or more generic competitors in December 2010, when the 30-month stay period expires, absent any court decision preventing such a launch before then.

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

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

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***Our business is increasingly affected by pressures on drug pricing.***

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control spending even more tightly. These pressures are particularly strong given the lingering effects of the recent global economic and financial crisis. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. These ongoing pressures include government-imposed industry-wide price reductions, mandatory pricing systems, 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 and growing pressure on physicians to reduce the prescribing of patented prescription medicines. We expect these efforts to continue as healthcare payors around the globe in particular government-controlled health authorities, insurance companies and managed care organizations step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price cuts. Such initiatives include the current efforts in the US to enact healthcare reform.

These initiatives not only affect the results of our Pharmaceuticals Division, but also have an increasing impact on the prices we can charge for the generic drugs marketed by our Sandoz Division. This is particularly true in Europe and especially Germany, our second-largest market for generic products, where various measures have been introduced to require generic manufacturers to lower their prices. In addition, in the US, a combination of aggressive efforts by distributors and retailers to increase their profit margins on generic products that are considered commodities, intense and increasing competition between generic pharmaceutical manufacturers, and changes and potential future changes to government regulations, including state and federal regulations and regulations impacting Medicare and Medicaid, are increasing the downward pressure on our prices there. We expect these and other challenges to continue to put pressure on our revenues, and therefore they could have a material adverse effect on our business, financial condition and results of operations.

For more information on pricing controls and on our challenging business environment see "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls."

***Our research and development efforts may not succeed in bringing high-potential products to market.***

Our ability to continue to grow our business and to replace sales lost due to the end of market exclusivity depends upon the success of our research and development activities in identifying and developing high-potential breakthrough products that address unmet 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 various collaborations with third parties. Developing new pharmaceutical products and bringing them to market, however, is a costly, lengthy and uncertain process. In spite of our significant investments, there can be no guarantee that our research and development activities will produce a sufficient number of commercially viable new products.

The research and development process for a new pharmaceutical product can take up to 15 years, or even longer, from discovery to commercial product launch and with a limited available patent life the longer it takes to develop a product, the less time there will be for us to recoup our development costs. New products need not only undergo intensive preclinical and clinical testing, but also must pass a highly complex, lengthy and expensive approval process. During each stage, there is a substantial risk that we will encounter serious obstacles which will further delay us and add substantial expense, or that we will not achieve our goals and, accordingly, may be forced to abandon a product in which we have invested substantial amounts of time and money. Reasons for delays may include: failure of the product candidate in preclinical studies; difficulty enrolling patients in clinical trials or delays or clinical trial holds at clinical trial sites; delays in completing formulation and other testing and work necessary to support an

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application for regulatory approval; adverse reactions to the product candidate or indications of other safety concerns; insufficient clinical trial data to support the safety or efficacy of the product candidate; our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured. Similar efforts are required to develop new products in our other divisions, as well, and similar risks apply. For a description of the approval processes which must be followed to market our products, see the sections headed "Regulation" included in the descriptions of our four operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

The pharmaceuticals industry has seen a dearth of regulatory approvals for new drugs in recent years, coupled with a significant increase in the cost per drug approved. For example, the FDA approved only 26 entirely new drugs (new molecular entities) in 2009. This follows 24 new approvals in 2008 and only 18 in 2007, one of the lowest single-year totals since 1983, when there were 14. These approval levels compare with the average annual approval rate of more than 30 new medicines per year in the period from 1996 to 2004. In addition, many of the new drugs approved in recent years have not been as financially successful as those approved in prior years. This relatively low level of research productivity comes at a time when the worldwide pharmaceuticals industry is estimated to be spending nearly $50 billion each year on research and development activities, according to the Tufts Center for the Study of Drug Development. As a result, industry research and development spending per new molecular entity approved has climbed more than 200% to $3.7 billion for 2006 2008 compared to only $1.2 billion for 1998 2000.

If we are unable to maintain a flow of successful new products and new indications for existing products sufficient to cover our substantial research and development costs and to replace sales lost as older products are lost to generic competition, or displaced by competing products or therapies including the significant number of important products likely to face generic competition in the near future this could have a material adverse effect on our business, financial condition or results of operations.

In addition, we invest a significant amount of effort and financial resources into research and development collaborations with third parties organizations that we do not control. Many of these may be small companies that do not have the same resources and development expertise as Novartis. If these third parties fail to meet our expectations, we may lose our investment in the collaborations or fail to receive the expected benefits, which could have a material adverse effect on our business, financial condition or results of operations.

***Increasing regulatory scrutiny of drug safety and efficacy may adversely affect us.***

Following several widely publicized issues in recent years, health regulators are increasingly focusing on product safety. Recently, the Obama Administration has publicly emphasized the importance of enforcing US drug safety regulations. In addition, authorities have paid increased attention to the risk/benefit profile of pharmaceutical products. These developments have led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analysis of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals for pharmaceutical products has become even more challenging.

In addition, the post-approval regulatory burden has been increasing. Approved drugs have increasingly been subject to requirements such as risk evaluation and mitigation strategies, comparative effectiveness studies and requirements to conduct post-approval Phase IV clinical trials to gather far more detailed safety and other data on products. These requirements have the effect of making the maintenance of regulatory approvals increasingly expensive, and further heightening the risk of recalls or loss of market share.

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These regulatory requirements, and any additional adverse regulatory developments in the approval process for new products or in the continued marketing of significant existing products, or any increases in regulation or major changes in the healthcare landscape, could have a material adverse effect on our business, financial condition and results of operations.

***Legal proceedings may have a significant negative effect on our results of operations.***

We are obligated to comply with the laws of the approximately 140 countries in which we operate, covering an extremely wide range of activities. To that end, we have a strong global compliance with law program in place. Nonetheless, in recent years, there has been a trend of increasing litigation and government investigations against companies operating in the industries of which we are a part, especially in the US. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including proceedings regarding product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, sales and marketing practices, health and safety, environmental, tax, privacy, and intellectual property matters. As a result, we may become subject to substantial liabilities that may not be covered by insurance. Litigation is inherently unpredictable, and large verdicts sometimes occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations or cash flows.

In particular, governments and regulatory authorities have been stepping up their compliance and law enforcement activities in recent years in key areas, including corruption, marketing practices, antitrust and trade restrictions. Responding to such investigations is costly, and a significant diversion of management's attention from our business. In addition, such investigations may affect our reputation and create a risk of potential exclusion from US federal government reimbursement programs. These factors have contributed to decisions by us and other companies in our industry to enter into settlement agreements with governmental, and particularly federal, authorities. Those settlements have involved and may continue to involve very large cash payments, including the potential repayment of amounts allegedly obtained improperly and penalties up to treble damages. In addition, settlements of healthcare fraud cases often require companies to enter into a corporate integrity agreement, which is intended to regulate company behavior for a period of years. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

Our businesses have been subject, from time to time, to such governmental investigations and information requests by regulatory authorities. For example, we have been cooperating with parallel civil and criminal investigations by the US Attorney's Office for the Eastern District of Pennsylvania (EDPA) into allegations of potential off-label marketing and promotion of our epilepsy drug, *Trileptal,* as well as certain payments made to healthcare providers in connection with this medicine. one of our affiliates recently entered into a plea agreement with the EDPA, which is contingent on court approval, to resolve criminal allegations. Pursuant to the plea agreement, the affiliate will plead guilty to a misdemeanor violation of the US Food, Drug and Cosmetic Act and pay $185 million. The affiliate is currently negotiating with the EDPA to resolve civil claims relating to *Trileptal.* In the fourth quarter of 2009, we increased provisions relating to the EDPA's *Trileptal* investigation by $318 million. Total provisions relating to the EDPA's civil and criminal *Trileptal* investigations were $397 million. Our affiliate is also cooperating with an investigation by the EDPA regarding potential off-label marketing and promotion as well as payments made to healthcare providers in connection with five other products: *Diovan, Exforge, Sandostatin, Tekturna* and *Zelnorm.* We are unable to assess with reasonable certainty the outcome of the investigation related to these five products or the amounts, which could be material, that we might be required to pay to resolve this investigation.

At the same time, our Sandoz Division may, from time to time, seek approval to market a generic version of a product before the expiration of patents claimed by one of our competitors for the branded product. We do this in cases where we believe that the relevant patents are invalid, unenforceable, or

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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.

Separately, the US affiliates of our Pharmaceuticals and Sandoz Divisions are the subjects of lawsuits brought by private plaintiffs and a number of state and local governments alleging that they have fraudulently overstated the Average Wholesale Price and "best price," which are, or have been, used by the US federal and state governments in the calculation of, respectively, US Medicare reimbursements and Medicaid rebates. While a Novartis affiliate was successful on appeal in one of these actions, juries have awarded plaintiffs substantial damages in three trials against Novartis affiliates to date. More trials are expected in the future.

Adverse judgments or settlements in any of these cases could have a material adverse effect on our business, financial condition and results of operations.

In addition, in many countries, particularly less-developed markets, we rely heavily on third-party distributors and other agents for the marketing and distribution of our products. Many of these third parties are small and do not have internal compliance resources comparable to those within our organization. Some of these countries are plagued by corruption. If our efforts to screen our third-party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties with applicable laws and regulations, which may have a negative effect on our reputation and our business.

For more detail regarding specific legal matters currently pending against us and provisions for such matters, see "Item 18. Financial Statements  note 20."

***An increasing amount of intangible assets and goodwill on our books may lead to significant impairment charges in the future.***

The amount of goodwill and other intangible assets on our consolidated balance sheet has increased significantly in recent years, primarily due to acquisitions. Although no significant additional impairments are currently anticipated, impairment testing could lead to material impairment charges in the future.

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets, investments in associated companies and goodwill, for impairment. Goodwill, acquired research and development, and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. Impairment testing under IFRS may lead to impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing impact of impairment charges on our results of operations, see "Item 5.A Operating Results  Critical Accounting Policies and Estimates  Impairment of Long-Lived Intangible and Tangible Assets" and "Item 18. Financial Statements  note 11."

***Risks related to our expected acquisition of a majority interest in Alcon and subsequent merger with Alcon.***

On January 4, 2010, we announced that we had exercised our option obtained in 2008 to acquire Nestlé's remaining 52% majority stake in Alcon (such that, with the 25% we previously purchased from Nestlé, we would become a 77% shareholder of Alcon). We also separately proposed to enter into an all-share direct merger with Alcon to acquire the remaining 23% publicly-held stake.

Our acquisition of the 52% majority stake from Nestlé is conditioned upon the receipt of certain governmental clearances or approvals, including the expiration or termination of the applicable waiting period under the US Hart-Scott-Rodino Act, the issuance by the European Commission (EC) of a

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decision under the EC Merger Regulation declaring the merger compatible with the common market, and the clearance or approval of the merger by the antitrust regulators in a number of other countries. While Nestlé and Novartis have agreed to use their reasonable best efforts to obtain these clearances and approvals, there can be no assurance that they will be obtained, or that the governmental authorities will not seek to impose material conditions on the acquisition or require the divestment of material assets.

In addition, our proposed merger with Alcon is conditioned both on the completion of the 52% stake acquisition from Nestlé and on the approval by the Boards of Directors of Novartis and Alcon. The merger would also require two-thirds approval by the shareholders of Novartis and Alcon voting at their respective meetings. If the merger is delayed, the timing and/or realization of the anticipated benefits and cost savings from fully integrating the businesses of Novartis and Alcon will be adversely affected. Once the acquisition and merger with Alcon is approved and completed, its success will depend, in part, on the combined company's ability to realize these benefits and cost savings and to retain and motivate its executives and key employees.

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

As of December 31, 2009 we had $8.7 billion of non-current financial debt and $5.3 billion of current financial debt. In addition, we expect to increase our indebtedness by $16 billion to finance our acquisition of Nestlé's 52% stake in Alcon. Our current and future debt requires us to dedicate a portion of our cash flow to service interest and principal payments and may limit our ability to engage in other transactions and otherwise place us at a competitive disadvantage to our competitors that have less debt. We may have difficulty refinancing our existing debt or incurring new debt on terms that we would consider to be commercially reasonable, if at all.

***We may not be able to realize the expected benefits of our significant investments in emerging growth markets.***

At a time of slowing growth in sales of pharmaceuticals in industrialized countries, many emerging markets have experienced comparatively strong economies, leading to proportionally higher growth and an increasing contribution to the industry's global performance. In 2009, we generated approximately 65% (2008: 64%) of our net sales from continuing operations in the world's seven largest developed markets, while the six leading emerging markets Brazil, China, India, Russia, South Korea and Turkey contributed 9% (2008: 9%) of net sales. However, combined net sales in these six priority emerging markets grew 17% in local currency in 2009, compared to 10% sales growth in local currency in the seven largest developed markets during the same period. As a result of this trend, we have been taking steps to increase our presence in these priority emerging markets and in other emerging markets. For example, a cross-divisional operating structure is being expanded following its initial implementation in 2007 to accelerate growth in smaller emerging markets and better position the comprehensive presence of all Novartis products. These types of markets include Northern and Sub-Saharan Africa, Central Asia and some countries in Southeast Asia.

There is no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will continue to experience growth rates in excess of the world's largest markets. Some emerging countries may be especially vulnerable to the after-effects of the recent global financial crisis, or may have very limited resources to spend on healthcare. See " The after-effects of the recent economic and financial crisis may have a material adverse effect on our results" below. Many of these countries have a relatively limited number of persons with the skills and training suitable for employment at an enterprise such as ours. See also " An inability to attract and retain qualified personnel could adversely affect our business" below. In other emerging countries, we may be required to rely on third-party agents, which may put us at risk of liability. See also " Legal proceedings may have a significant negative effect on our results of operations" above. 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.

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***The after-effects of the recent global economic and financial crisis may have a material adverse effect on our results.***

Many of the world's largest economies and financial institutions continue to be impacted by the recent global economic and financial crisis, with some continuing to face financial difficulty, a decline in asset prices, liquidity problems and limited availability of credit. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. Such uncertain economic times may have a material adverse effect on our revenues, results of operations, financial condition and ability to raise capital. Some of our businesses, including the business units of our Consumer Health Division, may be particularly sensitive to declines in consumer spending. In addition, our Pharmaceuticals, Vaccines and Diagnostics, and Sandoz Divisions may not be immune to consumer cutbacks, particularly given the increasing requirements that patients pay a larger contribution toward their own healthcare costs. As a result, there is a risk that consumers may cut back on prescription drugs and vaccines, as well as consumer health products, to help cope with rising costs and difficult economic times.

The economic crisis may also lead to a disruption or delay in the performance of third parties on which we rely for parts of our business, including licensees and collaboration partners, distributors, clinical trial providers and suppliers of products, intermediates and other goods or services. Such disruptions or delays could have an adverse effect on our business and results of operations.

In addition, the varying impact of difficult economic times on the economies of different countries has impacted, and may continue to unpredictably impact, the translation of our operating results into US dollars, our reporting currency. The financial crisis may also cause the value of our investments in our pension plans to decrease, requiring us to increase our funding of those pension plans. In addition, the financial crisis may also result in a lower return on our financial investments, and a lower value on some of our assets. The financial crisis could also negatively impact the cost of financing or our ability to finance the second step of the Alcon acquisition on favorable terms.

At the same time, significant changes and volatility in the consumer environment, the equity, credit and foreign exchange markets, and in the competitive 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, under current market conditions there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

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

Our Sandoz Division achieves significant revenue opportunities when it secures and maintains exclusivity periods granted for generic products in certain markets particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act and when it is able to develop differentiated, "difficult-to-make" products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz. In addition, the division faces intense competition from branded pharmaceuticals companies, which commonly take aggressive steps to limit the availability of exclusivity periods or to reduce their value. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction.

***Sandoz may not be able to realize the expected benefits of our significant investments in "biosimilar" drugs.***

Sandoz has made, and expects to continue to make, significant investments in the development of biotechnology-based products intended for sale as bioequivalent or "biosimilar" generic versions of

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currently marketed biotechnology products. The development of such products is costly and complex. In addition, to date, many countries, most notably the US, do not yet have a legislative or regulatory pathway which would permit such products to be sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Significant delays in the development of such pathways, or significant impediments that may be built into such pathways, could diminish the value of the investments that Sandoz has made, and will continue to make, in its biotechnology operations.

There is no guarantee that our efforts to develop and market these products will be successful or that we will be able to realize the expected benefits from our significant investment in this area. A failure to build and expand our position in biosimilars or to achieve the expected benefits from our investments in this area could have an adverse effect on our business, financial condition and results of operations.

***A failure to develop differentiated vaccines or to bring key products to market in time for the relevant disease seasons could have an adverse effect on the success of our Vaccines and Diagnostics Division.***

The demand for some products marketed by our Vaccines and Diagnostics Division, such as influenza vaccines, is seasonal, while the demand for other vaccines, such as pediatric combination vaccines, depends on changes in birth rates in developed countries. Some vaccines that make an important contribution to the division's net sales and profits, particularly the key seasonal influenza vaccine products, are considered commodities, meaning that there are few therapeutic differences among the vaccines offered by competitors. As a result, these vaccines may suffer from price erosion due to excess product supply across the industry, or from intense price competition. In addition, the market for pandemic and seasonal influenza vaccines is experiencing an unprecedented period of significant volatility given the global A (H1N1) influenza pandemic. While deliveries of pandemic vaccines provided significant contributions to results in 2008 (from A (H5N1) vaccines) and 2009 (from A (H1N1) vaccines), no guarantee can be made that these types of influenza vaccines will provide contributions in 2010 and the future. The ability to develop differentiated, effective and safe vaccines, to gain approval for inclusion in national immunization recommendation lists, and to consistently produce and deliver high-quality vaccines in time for the relevant disease seasons are critical to the success of our Vaccines and Diagnostics Division. In particular, our Vaccines and Diagnostics Division has been working to develop two vaccines to combat different strains of meningococcal meningitis. These products are the primary products in the division's pipeline. If our Vaccines and Diagnostics Division were unable to successfully develop one or both of these products, or if the approval of either or both of these products were significantly delayed, it could have a material adverse effect on the medium- to long-term success of the division.

***Our OTC Business Unit faces adverse impacts from increased competition, as well as potential questions of safety and efficacy.***

The OTC Business Unit of our Consumer Health Division sells over-the-counter medicines, many of which contain ingredients also sold by competitors in the OTC industry. Particularly in the US, our branded OTC products compete against "store brand" products that are made with the same active ingredients as ours. These products do not carry our trusted brand names, but they also do not carry the burden of the expensive advertising and marketing that helped to establish demand for the product. As a result, the store brands may be sold at lower prices. In recent years, consumers have increasingly begun to purchase store brand OTC products instead of branded products. In addition, in recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain products sold by our OTC Business Unit and its competitors. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. For example, in October 2008, acting in consultation with the FDA, we voluntarily re-labeled our US cough and cold medicines to indicate that these products should not be used in children under four years of age. Litigation has often followed actions such as these, particularly in the US. Additional actions and litigation regarding OTC products are possible in the future. These trends have had, and may continue to have, a significant adverse effect on the success of our OTC

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Business Unit. See also " The after-effects of the recent economic and financial crisis may have a material adverse effect on our results" above.

***The manufacture of our products is highly regulated and complex, and may encounter a variety of issues that lead to supply disruptions.***

The products we market, distribute and sell are either manufactured at our own dedicated manufacturing facilities or by third parties. In either case, we need to ensure that manufacturing processes comply with applicable regulations and manufacturing practices, as well as our own high quality standards. In particular, the manufacture of our products is heavily regulated by governmental authorities around the world, including the FDA. If we or our third-party suppliers fail to comply fully with such regulations then there could be a government-enforced shutdown of production facilities or production lines, which in turn could lead to product shortages. A failure to comply fully with such regulations could also lead to a delay in the approval of new products. For example, in August 2008, our Wilson, North Carolina facility received a Warning Letter from the FDA that raised concerns regarding the Wilson facility's compliance with FDA Good Manufacturing Practice regulations, and stated that until the FDA confirmed that the deficiencies had been corrected, the FDA could recommend disapproval of any pending NDAs, abbreviated NDAs or export certificate requests submitted by our Sandoz US affiliate. Voluntary recalls were made in September and in the fourth quarter of 2008 as part of the FDA review of the facility. While this Warning Letter was resolved in August 2009 following a successful FDA inspection, there can be no guarantee that we will not face similar issues in the future, or that we will successfully manage such issues when they arise.

In addition, 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. As a result of these factors, the production of one or more of our products may be disrupted from time to time.

A disruption in the supply of certain key products, or our failure to accurately predict demand, could have a material adverse effect on our business, financial condition or results of operations. And because our products are intended to promote the health of patients, for some of our products, a supply disruption could subject us to lawsuits or to allegations that the public health, or the health of individuals, has been endangered.

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

We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. We are required to make significant assumptions and estimates about future events in calculating the present value of expected future expense and liability related to these plans. These include assumptions about discount rates we apply to estimated future liabilities, expected returns on plan assets and rates of future compensation increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by Novartis may differ materially from the actual results we experience due to changing market and economic conditions (including the effects of the recent global economic and financial crisis), higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the discount rate we apply in determining the present value of expected future obligations of one-half of one percent would have increased our year-end defined benefit obligation by $1.1 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and

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Estimates Retirement and other post-employment plans" and "Item 18. Financial Statements note 25". See also " The after-effects of the recent economic and financial crisis may have a material adverse effect on our results" above.

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

The integrated nature of our worldwide operations enables us to reduce the effective tax rate on our earnings because a portion of our earnings are taxed at more favorable rates in some jurisdictions. Changes in tax laws or their application with respect to matters such as transfer pricing, intercompany dividends, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, could increase our effective tax rate and adversely affect our financial results.

***Ongoing consolidation among our distributors may increase both the purchasing leverage of key customers and the concentration of credit risk.***

Increasingly, a significant portion of our global sales are made to a relatively small number of US drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally are all in the US, and accounted for approximately 8%, 7% and 6%, respectively, of Group net sales from continuing operations in 2009. The largest trade receivables outstanding were for these three customers, amounting to 9%, 6% and 6%, respectively, of the Group's trade receivables at December 31, 2009. The trend has been toward further consolidation among our distributors, especially in the US. As a result, our distributors are gaining additional purchasing leverage, which increases the pricing pressures facing our businesses. Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantially greater than in the past. This could have a material adverse effect on our business, financial condition and results of operations.

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

We highly depend upon skilled personnel in key parts of our organization, and we invest heavily in recruiting and training qualified individuals. The loss of the service of key members of our organization particularly senior members of our scientific and management teams could delay or prevent the achievement of major business objectives. In addition, the success of our research and development activities is particularly dependent on our ability to attract and retain sufficient numbers of high-quality researchers and development specialists.

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

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

We face intense competition for an increasingly limited pool of qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research

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institutions. As a result, we may be unable to attract and retain qualified individuals in sufficient numbers, which would have an adverse effect on our business, financial condition and results of operations.

***Environmental liabilities may adversely impact our results of operations.***

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

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

In the recent past, the US dollar, our reporting currency, has suffered significant decreases in value against other world currencies. Because a significant portion of our earnings and expenditures are in currencies other than the US dollar, these decreases have had a significant impact on our reported net sales and earnings. In 2009, 35% of our net sales from continuing operations were made in US dollars, 31% in euros, 8% in Japanese yen, 3% in Swiss francs and 23% in other currencies. During the same period, 33% of our expenses from continuing operations arose in US dollars, 31% in euros, 12% in Swiss francs, 4% in Japanese yen and 20% in other currencies. As has happened in the recent past, changes in exchange rates between the US dollar and other currencies can result in increases or decreases in our sales, costs and earnings. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured in US dollars and the components of shareholders' equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5.A Operating Results  Effects of Currency Fluctuations" and "Item 11. Quantitative and Qualitative Disclosures about Non-Product-Related Market Risk." See also "  The after-effects of the recent economic and financial crisis may have a material adverse effect on our results" above.

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

Our business is increasingly dependent on increasingly complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and computer viruses which may result in the loss of key information or impairment of production and business processes. Data security breaches  whether by employees or others  may expose sensitive data to unauthorized persons. Such disruptions and breaches of security could materially and adversely affect our business.

***Earthquakes could adversely affect our business.***

Our corporate headquarters, the headquarters of our Pharmaceuticals and Consumer Health Divisions, and certain of our major Pharmaceuticals Division production facilities are located near earthquake fault lines in Basel, Switzerland. In addition, other major facilities of our Pharmaceuticals, Vaccines and Diagnostics, Sandoz and Consumer Health Divisions are located near major earthquake fault lines in various locations around the world. In the event of a major earthquake, we could experience business interruptions, destruction of facilities and loss of life, all of which could have a material adverse effect on our business, financial condition and results of operations.

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**Risks Related To Our ADSs**

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

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

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

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

## Item 4. Information on the Company

### 4.A History and Development of Novartis

**Novartis AG**

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

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

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The Novartis Group is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of healthcare products led by innovative pharmaceuticals. Novartis AG, our Swiss holding company, owns, directly or indirectly, 100% of all significant operating companies. For a list of our significant operating subsidiaries, see "Item 18. Financial Statements note 31."

**Important Corporate Developments 2007-January 2010**

The following is an overview of certain important developments between 2007 and January 2010:

***2010***

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| January | Novartis announces its intention to gain full ownership of Alcon Inc. by first completing the April 2008 agreement with Nestlé S.A. to acquire a 77% majority stake in Alcon, and subsequently entering into an all-share direct merger with Alcon for the remaining 23% minority stake. |

***2009***

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| December | Novartis enters into an agreement to acquire Corthera Inc. for $120 million plus potential milestone payments related to the successful development and commercialization of relaxin, a potential treatment for acute decompensated heart failure. The agreement is subject to regulatory approvals. |
| | Novartis licenses to Prometheus Laboratories the rights to sell *Proleukin* in the US, commencing in February 2010. Novartis retains the right to sell *Proleukin* outside of the US. |
| November | Novartis announces $1 billion investment over the next five years to significantly expand the China Novartis Institutes for BioMedical Research so that it would become the largest pharmaceutical research and development institute in China, and the third largest Novartis research institute worldwide. |
| | Novartis enters into agreement to acquire 85% stake in Chinese vaccines company Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd., which offers marketed vaccine products in China and research and development projects focused on viral and bacterial diseases, for $125 million. |
| | Novartis opens large-scale flu cell culture vaccine and adjuvant manufacturing facility in Holly Springs, North Carolina, in partnership with US Department of Health and Human Services, Biomedical Research and Development Authority. |
| | Novartis announces agreement to obtain rights outside the US to INC424, a promising Janus kinase inhibitor in Phase III development as well as worldwide rights to potential c-Met inhibitor compound, from Incyte Corporation for a combined upfront payment of $150 million as well as an immediate $60 million milestone payment and rights to potential future milestone payments and royalties based on future sales. |
| October | Novartis gains exclusive worldwide rights to PTK796, a potential first-in-class IV and oral broad-spectrum antibiotic in Phase III development, from Paratek Pharmaceuticals for upfront payment and eligibility for future milestone payments as well as royalties based on future sales. |

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| | Novartis enters into agreement for exclusive US and Canadian rights to *Fanapt*, an FDA-approved oral therapy for schizophrenia, with Vanda Pharmaceuticals Inc. for an upfront payment of $200 million, eligibility for additional milestone payments and sales royalties. |
| June | Novartis completes an open offer to acquire an additional stake in its majority-owned Indian subsidiary, Novartis India Ltd., increasing its holding to nearly 76.4% from the previous level of 50.9%. The transaction represented a total value of approximately $80 million. |
| | Novartis successfully launches a EUR 1.5 billion notes issue. |
| May | Novartis signs definitive agreement to acquire for EUR 925 million ($1.3 billion) the specialty generic injectables business of EBEWE Pharma, providing Sandoz the Group's generics division an opportunity to create a global platform for growth while improving access for patients to many generic oncology medicines. The transaction closed in September. |
| February | Novartis gains worldwide rights to elinogrel (PRT128), a Phase II anti-clotting compound with potential to reduce risk of heart attack and stroke, from Portola Pharmaceuticals Inc. for an upfront payment of $75 million and rights to future milestone payments and royalties based on future sales. |
| | Novartis successfully completes a $5 billion debt offering in the US. |

***2008***

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| October | Novartis enters into an agreement to acquire the pulmonary business unit of Nektar Therapeutics for $115 million. The transaction closed in December. |
| July | Novartis acquires majority ownership in Speedel, a Swiss-based pharmaceuticals company, and commits to acquire all remaining shares in a mandatory public tender offer (completed in September 2008), with total costs estimated at approximately $888 million. |
| | Novartis enters into a strategic partnership with Lonza, a Swiss pharmaceuticals manufacturing company, to accelerate growth of its biologic pharmaceuticals pipeline. |
| June | Novartis gains rights to PTZ601, a promising hospital antibiotic in clinical development, through the full acquisition of Protez Pharmaceuticals for $102 million in total and potential future payments of an additional $300 million. |
| | Two Swiss franc bonds are successfully issued totaling CHF 1.5 billion. |
| April | Novartis strengthens its healthcare portfolio through an agreement with Nestlé S.A. under which Novartis obtained the right to acquire majority ownership in Alcon Inc., the world leader in eye care, including pharmaceutical, surgical and consumer products, in two steps. In the first step, completed in July 2008, Novartis acquired a 25% stake in Alcon from Nestlé for $10.4 billion. The optional second step provides Novartis the right to buy, and Nestlé the right to sell, the remaining 52% stake in Alcon held by Nestlé between January 2010 and July 2011 for up to approximately $28 billion. |

***2007***

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| December | Novartis announces a new strategic initiative called "Forward" to enhance productivity by simplifying organizational structures, accelerating and decentralizing decision-making |

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| | and redesigning the way we operate. Through this initiative, we aim to reduce our cost base by approximately $1.6 billion by 2010 compared to 2007 levels. The initiative resulted in a restructuring charge of $444 million. |
| November | Novartis completes its fifth share repurchase program, initiated in July 2007. A total of 63,173,000 Novartis shares were repurchased for CHF 4 billion. |
| October | Novartis Biologics is established as a focused unit to accelerate and optimize research and development of innovative biologic medicines, which make up 25% of the Novartis pre-clinical product pipeline. |
| September | Novartis completes the sale of its Gerber Business Unit to Nestlé for $5.5 billion. |
| | Novartis and Bayer Schering Pharma AG (Bayer Schering) receive regulatory approval to complete an agreement related to various rights for the multiple sclerosis treatment Betaseron®. Novartis received a one-time payment of approximately $200 million, principally for manufacturing facilities transferred to Bayer Schering, and received rights to market its own version of Betaseron® starting in 2009. |
| July | Novartis completes the sale of its Medical Nutrition Business Unit to Nestlé for $2.5 billion. Novartis enhances vaccines pipeline by gaining access to Intercell's key technologies and vaccines programs through an expanded strategic alliance. |
| | Novartis completes its fourth share repurchase program, initiated in August 2004. A total of 47,575,000 Novartis shares were repurchased for CHF 3 billion. |
| April | Novartis announces a definitive agreement to divest Gerber to Nestlé for $5.5 billion, the final step in a divestment program to focus the Group's strategy on healthcare, with pharmaceuticals at the core. |

For information on our principal expenditures on property, plants and equipment, see "Item 4. Information on the Company 4.D Property, Plants & Equipment." For information on our significant investments in research and development, see the sections headed "Research and Development" included in the descriptions of our four operating divisions under "Item 4. Information on the Company 4.B Business Overview."

## 4.B Business Overview

### OVERVIEW

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our broad portfolio includes innovative medicines, preventive vaccines and diagnostic tools, generic pharmaceuticals and consumer health products. Novartis is the only company to have leadership positions in each of these areas.

The Group's businesses are organized in four global operating divisions:

Pharmaceuticals: Innovative patent-protected prescription medicines

Vaccines and Diagnostics: Human vaccines and blood-testing diagnostics

Sandoz: Generic pharmaceuticals

Consumer Health: OTC (over-the-counter medicines), Animal Health and CIBA Vision (contact lenses and lens-care products)

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Our strategy is to strengthen this healthcare portfolio through sustained investments in innovation, as well as through targeted acquisitions. In April 2008, we announced a significant agreement with Nestlé S.A. providing the right to acquire 77% majority ownership of Alcon Inc. (NYSE: ACL) in two steps and add this world leader in eye care to our portfolio. In July 2008, the first step was completed when Novartis acquired a 25% stake in Alcon for $10.4 billion in cash. On January 4, 2010, Novartis announced its intention to gain full ownership of Alcon Inc. (NYSE: ACL) by first completing the April 2008 agreement with Nestlé S.A. by taking the second step and acquiring Nestlé's remaining 52% majority stake in Alcon, and subsequently entering into an all-share direct merger with Alcon for the remaining 23% minority stake. Novartis believes this proposed merger, which would be implemented under the Swiss Merger Act, is in the interest of all stakeholders and will provide the needed clarity on Alcon's future. Alcon is expected to strengthen the Group's portfolio focused on healthcare and provide greater access to the fast-growing global eye care sector. Following the expected successful completion of the merger, Alcon would be established as a new Novartis division that incorporates Novartis and Alcon's highly complementary eye care assets.

Novartis completed the divestment of its remaining non-healthcare businesses in 2007 with the sale of the Medical Nutrition (effective July 1) and Gerber (effective September 1) Business Units, which were previously included in the Consumer Health Division. These businesses were sold in separate transactions to Nestlé S.A.

Novartis achieved net sales of $44.3 billion in 2009, while net income amounted to $8.5 billion. We invested $7.5 billion in Research & Development in 2009.

Headquartered in Basel, Switzerland, we employed 99,834 full-time equivalent associates as of December 31, 2009, and have operations in approximately 140 countries around the world.

**Pharmaceuticals Division**

Our Pharmaceuticals Division researches, develops, manufactures, distributes and sells branded prescription medicines in the following therapeutic areas: Cardiovascular and Metabolism; Oncology; Neuroscience and Ophthalmics; Respiratory; Immunology and Infectious Diseases; and Other. The Pharmaceuticals Division is organized into global business franchises responsible for the development and marketing of various products, as well as a business unit called Novartis Oncology, responsible for the global development and marketing of oncology products. Novartis Oncology is not required to be disclosed separately as a segment since it shares common long-term economic perspectives, customers, research, development, production, distribution and regulatory factors with the rest of the division. In 2009, the Pharmaceuticals Division accounted for $28.5 billion, or 65%, of Group net sales, and for $8.4 billion, or 78%, of Group operating income (excluding Corporate income and expense, net).

**Vaccines and Diagnostics Division**

Our Vaccines and Diagnostics Division researches, develops, manufactures, distributes and sells preventive vaccines and diagnostic tools. Novartis Vaccines is a leading global developer and manufacturer of human vaccines. Key products include influenza, meningococcal, pediatric and travel vaccines. Novartis Diagnostics is a blood testing and molecular diagnostics business dedicated to preventing the spread of infectious diseases through novel blood-screening tools that protect the world's blood supply. In 2009, the Vaccines and Diagnostics Division accounted for $2.4 billion, or 5%, of Group net sales, and provided $372 million, or 3%, of the Group's operating income (excluding Corporate income and expense, net).

**Sandoz Division**

Our Sandoz Division is a leading global generic pharmaceuticals company that develops, manufactures, distributes and sells prescription medicines, as well as pharmaceutical and biotechnological active substances, which are not protected by valid and enforceable third-party patents. The Sandoz

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Division has activities in Retail Generics, Anti-Infectives, Biopharmaceuticals and Oncology Injectables (following the acquisition of EBEWE Pharma, which was completed in September 2009). In Retail Generics, Sandoz develops, manufacture, distributes and sells active ingredients and finished dosage forms of medicines, as well as supplying active ingredients to third parties. In Anti-Infectives, Sandoz develops, manufactures, distributes and sells 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, distributes and sells protein- or biotechnology-based products (known as "biosimilars" or follow-on biologics) and sells biotech manufacturing services to other companies. In Oncology Injectables, Sandoz develops, manufactures, distributes and sells cytotoxic products for the hospital market. Sandoz offers approximately 1,000 compounds in more than 130 countries. In 2009, Sandoz accounted for $7.5 billion, or 17%, of Group net sales, and for $1.1 billion, or 10%, of Group operating income (excluding Corporate income and expense, net).

**Consumer Health Division**

Our Consumer Health Division consists of three business units: OTC (over-the-counter medicines), Animal Health and CIBA Vision. Each has its own research, development, manufacturing, distribution and selling capabilities. However, none are material enough to the Group to be separately disclosed as a segment. OTC offers readily available consumer medicine. Animal Health provides veterinary products for farm and companion animals. CIBA Vision markets contact lenses and lens care products. The Medical Nutrition and Gerber Business Units, which were previously included in the Consumer Health Division, were divested during 2007. The results of these business units have been reclassified and disclosed in this Form 20-F as discontinued operations in all applicable periods. In 2009, the Consumer Health Division (excluding discontinued operations) accounted for $5.8 billion, or 13%, of Group net sales, and for $1.0 billion, or 9%, of Group operating income (excluding Corporate income and expense, net).

## PHARMACEUTICALS

**Overview**

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

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

Cardiovascular and Metabolism

Oncology (including Hematology and Molecular Diagnostics)

Neuroscience and Ophthalmics

Respiratory

Immunology and Infectious Diseases

Other

The Pharmaceuticals Division is organized into global business franchises responsible for the marketing of various products as well as a business unit called Novartis Oncology responsible for the global development and marketing of oncology products. The Oncology Business Unit is not required to be separately disclosed as a segment in our consolidated financial statements since it shares common long-term economic perspectives, customers, research, development, production, distribution and regulatory environments with the remainder of the Pharmaceuticals

Division. The Pharmaceuticals Division is the largest contributor among the four divisions of Novartis and reported consolidated net sales of $28.5 billion in 2009, which represented 65% of the Group's net sales from continuing operations.

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The division is made up of approximately 80 affiliated companies which together employed 56,310 full-time equivalent associates as of December 31, 2009, and sell products in approximately 140 countries. The product portfolio of the Pharmaceuticals Division includes more than 50 key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 145 potential new products, new indications or new formulations for existing products in various stages of clinical development.

**Pharmaceuticals Division Products**

The following table and summaries describe certain key marketed products and recently launched products in our Pharmaceuticals Division. While we intend to sell all of our marketed products throughout the world, not all products and indications are currently available in every country. Compounds and new indications in development are, unless otherwise indicated, subject to required regulatory approvals and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. For some compounds, the development process is ahead in the US; for others, development in one or more other countries or regions is ahead of that in the US. 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 addition, for some of our products, we are required to conduct post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the products under special conditions. See " Regulation" for further information on the approval process. Certain of the products listed below have lost patent protection or are otherwise subject to generic competition. Others are subject to patent challenges by potential generic competitors. See below and " Intellectual Property" for further information on the patent status of our Pharmaceuticals Division's products.

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***Key Marketed Products***

| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| **Cardiovascular and Metabolism** | *Diovan* | valsartan | Hypertension<br>Heart failure<br>Post-myocardial infarction | Capsule<br>Tablet |
| | *Diovan HCT/ Co-Diovan* | valsartan and hydrochlorothiazide | Hypertension | Tablet |
| | *Eucreas* | vildagliptin and metformin | Type 2 diabetes | Tablet |
| | *Exforge* | valsartan and amlodipine besylate | Hypertension | Tablet |
| | *Exforge HCT* | valsartan, amlodipine besylate and hydrochlorothiazide | Hypertension | Tablet |
| | *Galvus* | vildagliptin | Type 2 diabetes | Tablet |
| | *Lescol/ Lescol XL* | fluvastatin sodium | Hypercholesterolemia and mixed dyslipidemia in adults.<br>Secondary prevention of major adverse cardiac events. Slowing the progression of atherosclerosis<br>Heterozygous familial hypercholesterolemia in children and adolescents. | Capsule<br>Tablet |
| | *Lotensin/ Cibacen* | benazepril hydrochloride | Hypertension<br>Adjunct therapy in congestive heart failure<br>Progressive chronic renal insufficiency | Tablet |
| | *Lotensin HCT/ Cibadrex* | benazepril hydrochloride and hydrochlorothiazide | Hypertension | Tablet |
| | *Lotrel* | amlodipine besylate and benazepril hydrochloride | Hypertension | Capsule |
| | *Starlix* | nateglinide | Type 2 diabetes | Tablet |
| | *Tekturna/Rasilez* | aliskiren | Hypertension | Tablet |
| | *Tekturna HCT/Rasilez HCT* | aliskiren and hydrochlorothiazide | Hypertension | Tablet |
| | *Valturna* | aliskiren and valsartan | Hypertension | Tablet |

[1] Not all indications are available in all countries.

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| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| **Oncology** | *Afinitor* | everolimus | mTor inhibitor for advanced renal cell carcinoma | Tablet |
| | *Exjade* | deferasirox | Chronic iron overload due to blood transfusions | Dispersible tablet for oral suspension |
| | *Femara* | letrozole tablets/letrozole | Early breast cancer in postmenopausal women following surgery (upfront adjuvant therapy)<br>Early breast cancer in post-menopausal women following standard tamoxifen therapy (extended adjuvant therapy)<br>Advanced breast cancer in post-menopausal women (both as first- and second-line therapies) | Tablet |
| | *Gleevec/ Glivec* | imatinib mesylate/imatinib | Certain forms of chronic myeloid leukemia<br>Certain forms of gastrointestinal stromal tumor<br>Certain forms of acute lymphoblastic leukemia<br>Dermatofibrosarcoma protuberans<br>Hypereosinophilic syndrome<br>Aggressive systemic mastocytosis<br>Myelodysplastic/myeloproliferative diseases | Tablet |
| | *Proleukin* | aldesleukin | Metastatic renal cell carcinoma<br>Metastatic melanoma | Lyophilized powder for IV infusion upon reconstitution and dilution |
| | *Sandostatin LAR & Sandostatin SC* | octreotide acetate for injectable suspension & octreotide acetate | Acromegaly<br>Symptoms associated with carcinoid tumors and other types of gastrointestinal neuroendocrine and pancreatic tumors | Vial<br>Ampoule/pre-filled syringe |
| | *Tasigna* | nilotinib | Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec* | Capsule |
| | *Zometa* | zoledronic acid | Reduce or delay skeletal-related events from bone metastases (cancer that has spread to the bones) | zoledronic acid for injection/zoledronic acid 4 mg |

[1] Not all indications are available in all countries.

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| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| **Neuroscience and Ophthalmics** | *Clozaril/ Leponex* | clozapine | Treatment-resistant schizophrenia<br>Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and schizoaffective disorder | Tablet |
| | *Comtan* | entacapone | Parkinson's disease | Tablet |
| | *Exelon* & *Exelon* Patch | rivastigmine tartrate & rivastigmine transdermal system | Alzheimer's disease<br>Dementia associated with Parkinson's disease | Capsule<br>Oral solution<br>Transdermal patch |
| | *Extavia* | Interferon beta-1b | Single demyelinating event with active inflammatory processes and relapsing forms of Multiple Sclerosis | Subcutaneous injection |
| | *Fanapt* | iloperidone | Schizophrenia | Tablet |
| | *Focalin* & *Focalin XR* | dexmethylphenidate HCl & dexmethylphenidate modified release | Attention deficit hyperactivity disorder | Tablet<br>Capsule |
| | *Ritalin* & *Ritalin LA* | methylphenidate HCl & methylphenidate HCl modified release | Attention deficit hyperactivity disorder and narcolepsy<br>Attention deficit hyperactivity disorder | Tablet<br>Capsule |
| | *Lucentis* | ranibizumab | Wet age-related macular degeneration | Intravitreal injection |
| | *Stalevo* | carbidopa, levodopa and entacapone | Parkinson's disease | Tablet |
| | *Tegretol* | carbamazepine | Epilepsy<br>Pain associated with trigeminal neuralgia<br>Acute mania and bipolar affective disorders | Tablet<br>Chewable tablet<br>Oral suspension<br>Suppository |
| | *Trileptal* | oxcarbazepine | Epilepsy | Tablet<br>Oral suspension |
| | *Visudyne* | verteporfin | Wet age-related macular degeneration<br>Pathological myopia<br>Ocular histoplasmosis | Vial, intravenous infusion activated by non-thermal laser light |
| | *Zaditor/ Zaditen* | ketotifen | Allergic conjunctivitis | Eye drops |

[1] Not all indications are available in all countries.

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| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| **Respiratory** | *Foradil* | formoterol | Asthma<br>Chronic obstructive pulmonary disease | Aerolizer (capsules)<br>Aerosol |
| | *Tobi* | tobramycin | Pseudomonas aeruginosa infection in cystic fibrosis | Inhalation solution |
| | *Xolair* | omalizumab | Allergic asthma | Lyophilized powder for reconstitution as subcutaneous injection |
| **Immunology and Infectious Diseases** | *Certican/Zortress* | everolimus | Prevention of organ rejection (heart and kidney) | Tablet<br>Dispersible tablet for oral suspension |
| | *Coartem/ Riamet* | artemether and lumefantrine | Plasmodium falciparum malaria or mixed infections that include Plasmodium falciparum<br>Standby emergency malaria treatment | Tablet<br>Dispersible tablet for oral suspension |
| | *Cubicin* | daptomycin | Complicated skin and soft tissue infections (cSSTI)<br>Right-sided endocarditis (RIE) due to Staphylococcus aureus<br>Staphylococcus aureus bacteremia when associated with RIE or cSSTI | Powder for solution, injection or infusion |
| | *Ilaris* | canakinumab | Cryopyrin-associated periodic syndrome (CAPS) | Lyophilized powder for reconstitution |
| | *Lamisil* | terbinafine | Fungal infection of the skin and nails caused by dermatophyte fungi<br>Tinea capitis.<br>Fungal infections of the skin for the treatment of tinea corporis, tinea cruris, tinea pedis and yeast infections of the skin caused by the genus Candida (e.g. Candida albicans) | Tablet<br>Cream<br>DermGel<br>Solution<br>Spray |
| | *Myfortic* | mycophenolic acid/mycophenolate sodium, USP | Prevention of graft rejection following kidney transplantation | Tablet |
| | *Neoral* | cyclosporine, USP Modified | Prevention of rejection following organ and bone marrow transplantation<br>Non-transplantation autoimmune conditions such as severe psoriasis, nephrotic syndrome, severe rheumatoid arthritis, atopic dermatitis or endogenous uveitis | Capsule<br>Oral solution |

[1] Not all indications are available in all countries.

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| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| | *Reclast/ Aclasta* | zoledronic acid/zoledronic acid 5 mg | Treatment of osteoporosis in postmenopausal women to reduce the incidence of hip vertebral and non-vertebral fractures, and to increase bone mineral density<br>Prevention of clinical fractures after hip fracture in men and women<br>Treatment of osteoporosis in men<br>Treatment and prevention of glucocorticoid-induced osteoporosis<br>Prevention of postmenopausal osteoporosis<br>Treatment of Paget's disease of the bone | Intravenous infusion |
| | *Simulect* | basiliximab | Prevention of acute organ rejection in de novo renal transplantation | Vial for injection or infusion |
| | *Tyzeka/Sebivo* | telbivudine | Chronic hepatitis B | Tablet |
| | *Voltaren/Cataflam* | diclofenac sodium/potassium | Inflammatory forms of rheumatism<br>Pain management | Tablet<br>Capsule<br>Drop<br>Ampoule<br>Suppository<br>Gel<br>Powder in sachet<br>Transdermal patch |
| **Other** | *Combipatch/ Estalis/Estalis Sequi* | estradiol hemihydrate and norethisterone acetate | Treatment of symptoms of estrogen deficiency in postmenopausal women with an intact uterus<br>Prevention of osteoporosis in postmenopausal women with an intact uterus | Transdermal patch |
| | *Elidel* | pimecrolimus | Atopic dermatitis (eczema) | Cream |
| | *Estraderm TTS/ Estraderm MX* | estradiol hemihydrate | Treatment of signs and symptoms of estrogen deficiency due to menopause<br>Prevention of accelerated postmenopausal bone loss | Transdermal patch |
| | *Estragest TTS Sequidot* | estradiol hemihydrate and norethisterone acetate | Treatment of symptoms of estrogen deficiency in postmenopausal women with an intact uterus<br>Prevention of postmenopausal osteoporosis in women with an intact uterus | Transdermal patch |
| | *Enablex/Emselex* | darifenacin | Overactive bladder | Tablet |

[1] Not all indications are available in all countries.

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| Therapeutic area | Product | Common name | Indication[1] | Formulation |
|---|---|---|---|---|
| | *Famvir* | famciclovir | Acute herpes zoster including ophthalmic herpes zoster and decreased duration of post herpetic neuralgia<br>Acute treatment of first episode and recurrent genital herpes infections, and for the suppression of recurrent genital herpes<br>Treatment of recurrent herpes labialis (cold sores)<br>Indicated in immunocompromised patients with herpes zoster or herpes simplex infections | Tablet |
| | *Miacalcin/ Miacalcic* | salmon calcitonin | Osteoporosis<br>Bone pain associated with osteolysis and/or osteopenia<br>Paget's disease<br>Neurodystrophic disorders (synonymous with algodystrophy or Sudeck's disease)<br>Hypercalcemia | Nasal spray<br>Ampoule & multi-dose<br>Vial for injection or infusion |
| | *Vivelle Dot/ Estradot* | estradiol hemihydrate | Estrogen replacement therapy for the treatment of the symptoms of menopause<br>Prevention of postmenopausal osteoporosis | Transdermal patch |

(1) Not all indications are available in all countries.

**Selected Leading Products**

*Cardiovascular and Metabolism*

*Diovan* (valsartan), together with *Diovan HCT/Co-Diovan* (valsartan and hydrochlorothiazide), is the world's No. 1 selling branded high blood pressure medicine (IMS data). *Diovan* is the only agent in its class approved to treat all of the following: high blood pressure (including children 6-16 years), high-risk heart attack survivors and patients with heart failure. First launched in 1996, *Diovan* is available in more than 120 countries for treating high blood pressure, in more than 90 countries for heart failure, and in more than 70 countries for heart attack survivors. First launched in 1997, *Diovan HCT/Co-Diovan* is approved in over 100 countries worldwide. In July 2008, the FDA approved *Diovan HCT* for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In January 2009, *Co-Diovan* was approved for treatment of high blood pressure in Japan.

*Exforge* (valsartan and amlodipine besylate) is a single-pill combination of the angiotensin receptor blocker *Diovan* and the calcium channel blocker amlodipine besylate. First approved in Switzerland in 2006, and in the US and EU in 2007 for the treatment of high blood pressure, it is now approved in over 90 countries and available in more than 70. In July 2008, the FDA approved *Exforge* for the first-line treatment of hypertension in patients likely to need multiple drugs to achieve their blood pressure goals. *Exforge* was approved in Japan in January 2010. *Exforge HCT* (valsartan, amlodipine besylate and hydrochlorothiazide) is a new single pill combining three widely prescribed high blood pressure treatments ARB (valsartan), CCB (amlodipine) and HCT (hydrochlorothiazide). In April 2009, the FDA approved *Exforge HCT* for patients who have tried taking dual combinations of these classes without success. In September 2009, *Exforge HCT* was approved in Switzerland for patients uncontrolled on any dual therapy, and in October 2009 *Exforge HCT* was approved in the EU as substitution therapy for patients controlled on all three agents (individual or in combination).

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*Tekturna/Rasilez* (aliskiren), and *Valturna* (aliskiren and valsartan) are treatments for high blood pressure based on the first and only approved direct renin inhibitor. *Tekturna/Rasilez* was approved in the US and EU in 2007, and is now available in more than 80 countries. The product is known as *Tekturna* in the US and *Rasilez* in the rest of the world. We are investigating various *Tekturna/Rasilez* single-pill combination products. The first single-pill combination product, *Tekturna/Rasilez* with hydrochlorothiazide called *Tekturna HCT* was approved by the US in January 2008 and in the EU in January 2009, where it is known as *Rasilez HCT*. Another single-pill combination product, *Tekturna/Rasilez* with valsartan called *Valturna* in the US (and to be called *Rasival* in the EU) has been approved by the FDA and was launched in the US in October 2009. *Rasival* was filed with the EMEA in August 2009. In addition, we initiated the ASPIRE HIGHER clinical development program, the largest ongoing cardio-renal outcomes program worldwide, involving more than 35,000 patients in 14 trials. Data from the ALOFT (heart failure) and AVOID (kidney disease) studies, which are part of the ASPIRE HIGHER program, have been added to European product information. Also in Phase III development are *Tekturna/Rasilez* with the calcium channel blocker amlodipine besylate and a triple-combination therapy with *Tekturna/Rasilez*, amlodipine besylate and a diuretic.

*Galvus* (vildagliptin), an oral treatment for type 2 diabetes, and *Eucreas*, a single-pill combination of vildagliptin and metformin, have shown promising results during the rollout in Europe following approvals in 2007. *Eucreas* was the first single-pill combination product including a DPP-4 inhibitor and another medication to be launched in Europe. *Galvus* is currently approved in approximately 70 countries and launched in 37 countries. *Galvus* was approved in Japan in January 2010 under the tradename *Equa*. *Eucreas* is currently approved in approximately 50 countries and launched in more than 40, including markets in the EU, Latin America and Asia.

*Oncology*

*Gleevec/Glivec* (imatinib mesylate tablets/imatinib) is a signal transduction inhibitor approved to treat certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). First launched in 2001, *Gleevec/Glivec* is available in more than 90 countries. *Gleevec/Glivec* is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of CML. *Gleevec/Glivec* is approved in the US, EU and Japan to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL), a rapidly progressive form of leukemia; dermatofibrosarcoma protuberans, a rare solid tumor; hypereosinophilic syndrome and myelodysplastic/myeloproliferative diseases; and other rare blood disorders. In the US, *Gleevec/Glivec* is also approved for aggressive systemic mastocytosis. *Gleevec/Glivec* received EU and Swiss regulatory approval in 2009 as a post-surgery (adjuvant setting) therapy for GIST following the US approval in 2008. The *Gleevec/Glivec* International Patient Assistance Program is now available in 80 countries, and is currently providing access to *Gleevec/Glivec* for free to more than 20,000 patients worldwide.

*Tasigna* (nilotinib) is a signal transduction inhibitor of the tyrosine kinase activity of Bcr-Abl, Kit and the PDGF-receptor. Since 2007, *Tasigna* has gained regulatory approval in more than 80 countries including the US, the EU, Switzerland and Japan, to treat a form of chronic myeloid leukemia (CML) in chronic and/or accelerated phase patients resistant or intolerant to existing treatment including *Gleevec/Glivec*. Japanese approval was achieved in January 2009.

*Zometa* (zoledronic acid for injection/zoledronic acid 4 mg) is a leading treatment to reduce or delay skeletal-related events from bone metastases (cancer that has spread to the bones). First approved in the US in 2001, *Zometa* is available in more than 88 countries. *Zometa* is approved for the treatment of patients with multiple myeloma and patients with documented bone metastasis from solid tumors, including prostate, breast and lung tumors. *Zometa* is also approved in most key markets for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of

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calcium). Zoledronic acid, the active ingredient in *Zometa*, is also available under the trade names *Reclast/Aclasta* for use in non-oncology indications. *Zometa* and *Reclast/Aclasta* may face significant competition in 2010 from denosumab, a new product under development by Amgen.

*Femara* (letrozole tablets/letrozole) is a once-daily oral aromatase inhibitor for the treatment of early stage or advanced breast cancer in postmenopausal women. *Femara* was first launched in 1996 and is currently available in more than 90 countries. *Femara* is approved in the US, EU and other countries as adjuvant therapy for postmenopausal women with hormone receptor-positive early breast cancer. It is also approved in the US, EU and other countries as extended adjuvant therapy for early breast cancer in postmenopausal women who are within three months of completing five years of adjuvant tamoxifen therapy. *Femara* is also approved in the US, EU and other countries as first-line treatment for postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer, and as treatment for advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy. In some countries, *Femara* is approved as neo-adjuvant (pre-operative) therapy for early stage breast cancer. In Japan, *Femara* is approved for the treatment of all hormone receptor-positive breast cancer in postmenopausal women.

*Sandostatin SC/Sandostatin LAR* (octreotide acetate/octreotide acetate for injectable suspension) is indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of pituitary growth hormone in adults. *Sandostatin* is also indicated for the treatment of certain symptoms associated with carcinoid tumors and other types of gastrointestinal neuroendocrine and pancreatic tumors. *Sandostatin* was first launched in 1988 and is approved in more than 85 countries. *Sandostatin SC* faces worldwide generic competition. However, patent protection continues in major markets for *Sandostatin LAR*.

*Exjade* (deferasirox) is an oral iron chelator approved for the treatment of chronic iron overload due to blood transfusions in patients who have a wide range of underlying anemias. Patients with congenital and acquired chronic anemias, such as thalassemia, sickle cell disease and myelodysplastic syndromes require transfusions as support for their anemia. *Exjade* was first approved in 2005 and is now approved in more than 90 countries including the US, EU and Japan. Approval in China anticipated in 2010. *Exjade* recently received regulatory approvals in the US, EU, Switzerland, and other countries for a new 40 mg/kg dose which provides a new option for patients who require higher dose titration for iron chelation. A New Drug Application for a potential competitive oral iron chelation product is under review by FDA, seeking broad labeling, including cardiac benefits, with possible late 2010 launch. We submitted new safety information to health authorities worldwide in July and August 2009 regarding the use of *Exjade* in myelodysplastic syndrome (MDS) and malignant disease patients. New labeling approved in the EU in November 2009 provides guidance on the selection of appropriate MDS and malignant disease patients for *Exjade* therapy. The review of this data is ongoing by the FDA and other health authorities.

*Afinitor* (everolimus) is an oral inhibitor of the mTOR pathway. It was launched in March 2009 in the US following regulatory approval as the first therapy for patients with advanced renal cell carcinoma (advanced kidney cancer) after failure of treatment with sunitinib or sorafenib. European regulatory approval was received in August 2009 and Japanese approval was received in January 2010. Everolimus, the active ingredient in *Afinitor*, is also available outside of the US under the brand name *Certican* for use in transplantation.

*Other Pharmaceuticals Products*

*Lucentis* (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors. *Lucentis* is the first approved drug for wet age-related macular degeneration (AMD) that has been shown to improve vision and vision-related quality of life. *Lucentis* was approved in the US in June 2006 and the EU in January 2007. It is now approved in

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more than 75 countries. *Lucentis* is developed in collaboration with Genentech, which holds the rights to market the product in the US.

*Exelon* and *Exelon* Patch (rivastigmine tartrate): *Exelon* capsules have been available since 1997 to treat mild to moderate Alzheimer's disease (AD) in more than 70 countries. In 2006, *Exelon* became the only cholinesterase inhibitor to be approved for mild to moderate Parkinson's disease dementia in addition to AD in both the US and EU. *Exelon* Patch (rivastigmine transdermal system) was approved in 2007 in the US and EU and has been launched in more than 60 countries. The once-daily *Exelon* Patch has shown comparable efficacy to the highest recommended doses of *Exelon* capsules, with significant improvement in cognition and overall functioning compared to placebo.

*Neoral* (cyclosporine, USP Modified) is an immunosuppressant to prevent organ rejection following a kidney, liver or heart transplant. This micro-emulsion formulation of cyclosporine is also indicated for treating selected autoimmune disorders such as psoriasis and rheumatoid arthritis. First launched in 1995, *Neoral* is marketed in approximately 100 countries. This product is subject to generic competition.

*Voltaren/Cataflam* (diclofenac sodium/potassium/Resinate/Free Acid) is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions. *Voltaren/Cataflam* was first launched in 1973 and is available in more than 140 countries. This product, which is subject to generic competition, is marketed by the Pharmaceuticals Division in a wide variety of dosage forms, including tablets, drops, suppositories, ampoules and topical therapy. In addition, in various countries, our Consumer Health Division's OTC Business Unit markets low-dose oral forms and the topical therapy of *Voltaren* as over-the-counter (OTC) products.

*Lescol/Lescol XL* (fluvastatin sodium) are lipid-lowering drugs used to reduce cholesterol. *Lescol/Lescol XL* are indicated as an adjunct to diet for the treatment of hypercholesterolemia and mixed dyslipidemia in adults, and to reduce cholesterol in children over nine years and adolescents with heterozygous familial hypercholestrolemia. In addition, for patients with coronary artery disease, *Lescol/Lescol XL* are indicated for secondary prevention of major adverse cardiac events and to slow the progression of coronary atherosclerosis. *Lescol* was first launched in 1994 and *Lescol XL* in 2000. Both are available in more than 90 countries.

*Comtan, Stalevo* (entacapone, carbidopa, levodopa and entacapone) are indicated for the treatment of Parkinson's disease. *Stalevo* is indicated for certain Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations, known as "wearing off." *Stalevo* was approved in the US and EU in 2003, and is available from Novartis in more than 50 countries. *Comtan* (entacapone) is also indicated for the treatment of Parkinson's disease patients who experience end-of-dose wearing off and is marketed in approximately 50 countries under a licensing agreement with the Orion Corporation. *Stalevo* and *Comtan* were developed and are manufactured by Orion, and are marketed by Novartis and Orion in their respective territories.

*Ritalin, Ritalin LA, Focalin, Focalin XR* (methylphenidate HCl, methylphenidate HCl extended release, dexmethylphenidate HCl and dexmethylphenidate HCl extended release) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adults. *Ritalin* is also indicated for pediatric and adult narcolepsy. *Ritalin* was first marketed during the 1950's and is available in over 50 countries. *Ritalin LA* (long lasting) is available in 20 countries. *Focalin* comprises the active d-isomer of methylphenidate and therefore requires half the dose of Ritalin. *Focalin* and *Focalin XR* (extended release) are only available in the US, although *Focalin XR* was approved in Switzerland in December 2009. Immediate-release *Focalin* is subject to generic competition.

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*Reclast/Aclasta* (zoledronic acid 5 mg) is the first and only once-yearly bisphosphonate infusion for the treatment of different forms of osteoporosis. Sold as *Reclast* in the US and *Aclasta* in the rest of the world, the product is approved in 90 countries including the US, EU and Canada, and is the only osteoporosis treatment approved to reduce the incidence of fractures at all three key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. It is also approved in more than 80 countries for the treatment of Paget's disease of the bone for men and women. The *Reclast/Aclasta* label was expanded in the EU and US to include the reduction in the incidence of clinical fractures after a low trauma hip fracture. The EU has also approved *Aclasta* for the treatment of osteoporosis in men and for the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in men at increased risk of fracture. *Reclast* is also approved in the US as a treatment to increase bone mass in men with osteoporosis, the prevention and treatment of glucocorticoid-induced osteoporosis in men and women as well as for the prevention of osteoporosis in postmenopausal women. Zoledronic acid, the active ingredient in *Reclast/Aclasta*, is also available under the trade name *Zometa* for use in oncology indications.

*Tegretol* (carbamazepine) has been a mainstay for the treatment of epileptic seizures since 1962. Tegretol is also indicated in the US for the treatment of pain associated with trigeminal neuralgia, which is characterized by attacks of intense pain affecting the face, as well as for the treatment of acute mania and bipolar affective disorders in the EU. *Tegretol* is subject to generic competition.

*Foradil* (formoterol fumarate) is a long-acting bronchodilator that offers a fast onset and a 12-hour duration of action for patients with asthma and chronic obstructive pulmonary disease (COPD). It was first registered and launched in Europe in 1994. US approval was granted in 2001, and in 2002 we licensed *Foradil* in the US to Merck (formerly Schering Plough). Novartis markets and distributes *Foradil* in other areas of the world. *Foradil Aeroliser* is a single-dose dry powder inhaler. A pressurized metered-dose inhaler is also available in some countries. The patent on *Foradil* has expired.

*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.

*Lotrel* (amlodipine besylate and benazepril hydrochloride) is a high blood pressure treatment which is a single-pill combination of the angiotensin-converting enzyme (ACE) inhibitor benazepril, used in *Lotensin/Cibacen*, and the calcium channel blocker (CCB) amlodipine. Launched in 1995 and only available in the US, *Lotrel* received generic competition in May 2007 as a result of a "launch at risk" of a generic product by Teva Pharmaceuticals, despite a US patent valid until 2017. Our Sandoz Division has also launched an authorized generic version of this high blood pressure medicine. See " Intellectual Property" for further information.

*Trileptal* (oxcarbazepine) is an anti-epileptic drug for the treatment of partial seizures as adjunctive or monotherapy in both adults and children aged four years and above. In the US, *Trileptal* is approved for the treatment of epilepsy. *Trileptal* acts by stabilizing neuronal functions, thereby controlling and limiting the spread of seizures. It was first approved in Denmark in 1990, in the rest of the EU in 1999, and in the US in 2000. Today it is approved in over 100 countries. *Trileptal* is subject to generic competition.

*Xolair* (omalizumab) is the first humanized monoclonal antibody approved for the treatment of moderate to severe allergic asthma in the US in adolescents (aged 12 and above) and adults. It is approved for severe allergic asthma in the EU in children (aged 6 and above), adolescents, and adults. *Xolair* is approved in more than 80 countries, including the US in 2003 and the EU in 2005.

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*Xolair* is being jointly developed with Genentech and is co-promoted in the US by Novartis and Genentech.

*Extavia* (interferon beta-1b) is an injectable disease modifying therapy for relapsing forms of multiple sclerosis (MS). It is the Novartis brand of interferon beta-1b, a product also marketed by Bayer Healthcare Pharmaceuticals Inc. under the brand name Betaseron® in the US and by Bayer Schering Pharma under the brand name Betaferon® in the EU. Bayer Schering supplies the product to Novartis under a contract manufacturing arrangement. *Extavia* was approved in the EU in May 2008 and since January 2009 has been launched in more than 20 markets, including the US in September 2009. Additional launches are planned in 2010. *Extavia* represents the first entry of Novartis into the treatment of MS.

*Ilaris* (canakinumab) is a fully human monoclonal antibody providing specific and highly selective blockade of interleukin-1β (IL-1β), a cytokine linked to inflammation. *Ilaris* began Phase III development in 2007 for cryopyrin-associated periodic syndrome (CAPS), a group of rare disorders characterized by chronic recurrent fever, urticaria, occasional arthritis, deafness, and potentially life threatening amyloidosis. Clinical studies in CAPS patients treated with *Ilaris* show rapid and long-lasting clinical response. *Ilaris* was approved in the US, the EU and some other markets to treat children four years and older and adults with CAPS.

*Fanapt* (iloperidone) is a dopamine type 2 (D2) and serotonin type 2 (5-HT2A) receptor antagonist antipsychotic agent. *Fanapt* is indicated in the US for the acute treatment of schizophrenia in adults and was launched in January 2010. *Fanapt* belongs to the class of medication for schizophrenia known as atypical antipsychotics.

**Compounds in Development**

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

**Phase I:** First clinical trials of a new compound, generally performed in a small number of healthy human volunteers, to assess the clinical safety, tolerability as well as metabolic and pharmacologic properties of the compound.

**Phase II:** Clinical studies that are performed on patients with the targeted disease, with a view to continuing Phase I safety assessment in a larger group, to assess the efficacy of the drug in the patient population, and to determine the appropriate doses for further testing.

**Phase III:** Large scale clinical studies with several hundred to several thousand patients, to establish the safety and effectiveness of the drug for regulatory approval for indicated uses. Phase III trials may also be used to compare a new drug against a current standard of care, in order to evaluate the overall benefit risk relationship of the new drug.

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

The following table and summaries describe certain key compounds and new indications for existing products currently in Confirmatory development within our Pharmaceuticals Division

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| Project/Product | Common name | Mechanism of action | Potential indication/Disease area | Therapeutic area | Formulation/Route of administration | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| ABF656 | albinterferon alfa-2b | Interferon alpha-type activity (direct antiviral and immunomodulatory) | Chronic hepatitis C | Immunology and Infectious Diseases | Injection | US, EU (registration) |
| ACZ885 | canakinumab | Anti IL-1β monoclonal antibody | Refractory gout | Immunology and Infectious Diseases | Injection | 2010//III |
| | | | Systemic onset juvenile idiopathic arthritis | Immunology and Infectious Diseases | | 2011/III |
| | | | Type 2 Diabetes Mellitus | Cardiovascular and Metabolism | | 2012/II |
| AEB071 | sotrastaurin | Protein kinase C inhibitor | Prevention of organ rejection | Immunology and Infectious Diseases | Oral | ≥ 2013/II |
| | | | Psoriasis | | | ≥ 2013/II |
| AFQ056 | TBD | mGluR5 antagonist | L-dopa induced dyskinesia in Parkinson's disease | Neuroscience And Ophthalmics | Oral | 2012/II |
| AGO178 | agomelatine | MT1 and MT2 agonist and 5-HT2c antagonist | Major depressive disorder | Neuroscience And Ophthalmics | Oral dispersible | 2012/III |
| AIN457 | TBD | Anti IL-17 monoclonal antibody | Uveitis | Neuroscience And Ophthalmics | Subcutaneous Intravenous injection | 2011/III |
| | | | Psoriasis | Immunology and Infectious Diseases | | ≥ 2013/II |
| | | | Rheumatoid arthritis | Immunology and Infectious Diseases | | ≥ 2013/II |
| ASA404 | vadimezan | Tumor vascular disrupting agent | Non-small cell lung cancer | Oncology | Intravenous | 2011/III |
| BAF312 | TBD | Sphingosine-1-phosphate (S1P) receptor modulator | Multiple sclerosis | Neuroscience And Ophthalmics | Tablet | ≥ 2013/II |
| BGS649 | TBD | Aromatase inhibitor | Refractory endometriosis | Immunology and Infectious Diseases | Tablet | ≥ 2013/II |
| CAD106 | TBD | Beta-amyloid-protein immunotherapy | Alzheimer's disease | Neuroscience And Ophthalmics | Subcutaneous Intramuscular injection | ≥ 2013/II |

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|---|---|---|---|---|---|---|
| *Certican/Zortress* | everolimus | Growth-factor-induced immune cell proliferation inhibitor | Prevention of organ rejection kidney | Immunology and Infectious Diseases | Oral | US (registration) |
| | | | Prevention of organ rejection liver | | | 2011/III |
| *Diovan* and *Starlix* (free combination) | valsartan and nateglinide | ARB and insulin secretagogue | Prevention of new onset type 2 diabetes, cardiovascular morbidity and mortality (NAVIGATOR) | Cardiovascular and Metabolism | Oral | 2010/III |
| *Elidel* | pimecrolimus | Topical calcineurin inhibitor | Atopic dermatitis in infants | Other | Cream | 2011/III |

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| **Project/Product** | **Common name** | **Mechanism of action** | **Potential indication/Disease area** | **Therapeutic area** | **Formulation/Route of administration** | **Planned filing dates/Current phase** |
|---|---|---|---|---|---|---|
| EPO906 | patupilone | Microtubule depolymerization inhibitor | Ovarian cancer | Oncology | Intravenous | 2010/III |
| FTY720 | fingolimod | Sphingosine-1-phosphate receptor modulator | Multiple sclerosis | Neuroscience And Ophthalmics | Oral | US, EU (registration) |
| INC424 | TBD | Janus kinase (JAK) inhibitor | Myelofibrosis | Oncology | Oral | 2011/III |
| *Joicela* | lumiracoxib | Cyclooxygenase 2 inhibitor | Osteoarthritis | Immunology and Infectious Diseases | Oral | EU (registration) |
| LBH589 | panobinostat | Histone deactelylase inhibitor | Multiple Myeloma | Oncology | Oral | ≥ 2013/III |
| | | | Hodgkin's lymphoma | | | 2010/II |
| LCI699 | TBD | Aldosterone synthase inhibitor | Heart failure | Cardiovascular and Metabolism | Intravenous infusion | ≥ 2013/II |
| LCQ908 | TBD | Diacylglycerol acyl transferase-1 inhibitor | Type 2 Diabetes Mellitus | Cardiovascular and Metabolism | Tablet | ≥ 2013/II |
| LCZ696 | TBD | ARB/NEP inhibitor | Heart failure | Cardiovascular and Metabolism | Oral | ≥ 2013/III |
| LDE225 | TBD | Smoothened receptor/hedgehog signaling inhibitors | Gorlin's syndrome | Immunology and Infectious Diseases | Cream | 2010/II |
| *Lucentis* | ranibizumab | Anti-VEGF monoclonal antibody fragment | Diabetic macular edema | Neuroscience And Ophthalmics | Intravitreal injection | EU (registration) |
| | | | Retinal Vein occlusion | | | 2011/II |
| *Mycograb* | efungumab | Antibody fragment vs. fungal HSP90 | Invasive candidiasis | Immunology and Infectious Diseases | Intravenous infusion | ≥ 2013/III |
| NIC002 | TBD | Nicotine Qbeta therapeutic vaccine | Smoking cessation | Respiratory | Injection | ≥ 2013/II |
| NVA237 | glycopyrronium bromide | Long-acting muscarinic antagonist | Chronic obstructive pulmonary disease | Respiratory | Inhalation | 2011/III |
| PKC412 | midostaurin | Signal transduction inhibitor | Acute myeloid leukemia | Oncology | Oral | ≥ 2013/III |

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|---|---|---|---|---|---|---|
| | | | Aggressive systemic mastocytosis | | | 2011/II |
| PRT128 | elinogrel | P2Y12 inhibitor | Acute coronary syndrome, Chronic coronary heart disease | Cardiovascular and Metabolism | IV, Oral | ≥ 2013/II |
| PTK796 | TBD | Inhibition of bacterial protein synthesis | Complicated Staphylococcal skin and subcutaneous tissue infections | Immunology and Infectious Diseases | Intravenous, oral | 2012/III |
| PTZ601 | TBD | Inhibition of bacterial cell wall synthesis | Staphylococcal skin and subcutaneous tissue infections, Hospital acquired bacterial infections such as pneumonia | Immunology and Infectious Diseases | Intravenous infusion | 2012/II |

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| **Project/Product** | **Common name** | **Mechanism of action** | **Potential indication/Disease area** | **Therapeutic area** | **Formulation/Route of administration** | **Planned filing dates/Current phase** |
|---|---|---|---|---|---|---|
| QAB149 | indacaterol | Long-acting beta-2 agonist | Chronic obstructive pulmonary disease | Respiratory | Inhalation | EU (approved)<br>US (registration) |
| QAX028 | TBD | Long-acting muscarinic antagonist | Chronic obstructive pulmonary disease | Respiratory | Inhalation | ≥ 2013/II |
| QMF149 | indacaterol and mometasone furoate | Long-acting beta-2 agonist and inhaled corticosteroid | Chronic obstructive pulmonary disease | Respiratory | Inhalation | ≥ 2013/II |
| | | | Asthma | | | ≥ 2013/II |
| QTI571 (*Glivec*) | imatinib mesylate/imatinib | Signal transduction inhibitor | Pulmonary arterial hypertension | Respiratory | Oral | 2011/III |
| QVA149 | indacaterol and glycopyrronium bromide | Long-acting beta-2 agonist and long-acting muscarinic antagonist | Chronic obstructive pulmonary disease | Respiratory | Inhalation | 2012/II |
| RAD001 (*Afinitor)* | everolimus | mTOR inhibitor | Neuroendocrine tumors | Oncology | Tablet | 2010/III |
| | | | Tuberous Sclerosis Complex subependymal giant cell astrocytomas | | | 2010/III |
| | | | Tuberous Sclerosis Complex Angiomyolipoma | | | 2011/III |
| | | | Breast cancer, Estrogen receptor positive | | | 2012/III |
| | | | Breast cancer Her2-over-expressing, 1st line | | | ≥ 2013/III |
| | | | Breast Her2-over-expressing 2nd/3rd line | | | ≥ 2013/III |
| | | | Advanced Gastric Cancer | | | 2012/III |
| | | | Diffuse large B-cell lymphoma | | | ≥ 2013/III |
| | | | Solid tumors | | | ≥ 2013/II |

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| Project/Product | Common name | Mechanism of action | Potential indication/Disease area | Therapeutic area | Formulation/Route of administration | Planned filing dates/Current phase |
|---|---|---|---|---|---|---|
| SBR759 | TBD | Calcium-free polymeric iron (III)-based phosphate binder | Hyperphosphatemia | Immunology and Infectious Diseases | Powder for oral suspension | 2011/II |
| SMC021 | salmon calcitonin | Protects articular cartilage and strengthens subchondral bone | Osteoarthritis | Immunology and Infectious Diseases | Oral | 2011/III |
| | | Inhibition of osteoclast activity | Osteoporosis | | | 2011/III |
| SOM230 | pasireotide | Somatostatin analogue | Cushing's disease | Oncology | Subcutaneous injection | 2010/III |