

## **UNITED STATES**

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

## **FORM 20-F**

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

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2004 OR

□ TRANSITION 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)

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

Title of class

Name of each exchange on which registered

New York Stock Exchange, Inc.

American Depositary Shares each representing 1 share, nominal value CHF 0.50 per share, and shares

Securities 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:

#### 2,426,810,076 shares

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, as amended, 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 🖂 No 🗌 Not Applicable

Indicate by check mark which financial statement item the Registrant has elected to follow:

Item 17 □ Item 18 ⊠

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#### INTRODUCTION AND USE OF CERTAIN TERMS

Novartis AG and our 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, 2004. In this Form 20-F, references to "US dollars", "USD" or "\$" are to the lawful currency of the United States of America; and references to "CHF" are to Swiss francs.

In this Form 20-F, references to the "United States" or to "US" are to the United States of America, references to "Europe" are to all European countries (including Turkey, Russia and the Ukraine), references to the European Union ("EU") are to the European Union and its 25 member states and references to "Americas" are to North, Central (including the Caribbean) and South America, unless the context otherwise requires; references to "Novartis" or the "Group" are to Novartis AG and its consolidated affiliates; references to "associates" are to employees of our affiliates; references to the "FDA" are to the US Food and Drug Administration. All product names appearing in italics are trademarks of Group companies. Product names identified by a "®" or a """" are trademarks of other 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 operating company in the Group is legally separate from all other companies in the Group 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 company by whom the executive is employed, or to that company's board of directors.

We furnish to registered holders of Novartis AG shares ("shares") annual reports that include a description of operations and annual audited consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRS"). IFRS differs in certain significant respects from US Generally Accepted Accounting Principles ("US GAAP"). See "Item 18. Financial Statements note 32" for a description of the significant differences between IFRS and US GAAP. The financial statements included in the annual reports are examined and reported upon by our independent auditors. We make available to our shareholders, on our web page, quarterly interim press releases that include unaudited interim consolidated financial information prepared in conformity with IFRS with a reconciliation to US GAAP.

#### 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, relating to our business and the industries in which we operate. Certain forward looking statements can be identified by the use of forward looking terminology such as "believe," "expect," "may," "are expected to," "will," "will continue," "should," "would be," "seek" or "anticipate" or similar expressions or the negative thereof or other variations thereof or comparable terminology, or by express or implied discussions of strategy, plans or intentions. Such statements include express or implied descriptions of our investment and research and development programs and anticipated expenditures in connection therewith, and descriptions of new products, or new indications for existing products, which we expect to introduce, and anticipated customer demand for such products. Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performances or achievements that may be expressed or implied by such forward looking statements. 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 do not intend, and do not assume any obligation, to update any information or forward looking statements set out in this Form 20-F.

#### 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. Our consolidated financial statements ("consolidated financial statements") for the years ended December 31, 2004, 2003 and 2002 are included elsewhere in this Form 20-F. All financial data should be read in conjunction with "Item 5. Operating and Financial Review and Prospects" and our consolidated financial statements and accompanying notes which are included elsewhere in this Form 20-F. All financial data presented in this Form 20-F are qualified in their entirety by reference to the consolidated financial statements and such notes.

The consolidated financial statements used to create the selected consolidated financial data set forth below were prepared in accordance with IFRS. IFRS differs in certain respects from US GAAP. For a discussion of the significant differences between IFRS and US GAAP, see "Item 18. Financial Statements—Note 32."

	Year Ended December 31,					
	2004	2003	2002	2001	2000	2000 <sup>(1)</sup>
		(\$ milli	ons, except	per share	information	1)
INCOME STATEMENT DATA Amounts in accordance with IFRS: Net sales	28,247	24,864	20,877	18,762	20,997	16,986
Operating income	,	5,889	5,092	4,325	4,684	4,000
Result from associated companies	142 227	(200) 379	(7) 613	83 284	58 187	57 261
Income before taxes and minority interestsTaxesMinority interests			<b>5,698</b> (959) (14)	<b>4,692</b> (844) (12)	<b>4,929</b> (1,082) (25)	<b>4,318</b> (895) (15)
Net income	5,767	5,016	4,725	3,836	3,822	3,408
Basic earnings per share in $\$^{(2)}$ Diluted earnings per share in $\$^{(2)}$ Cash dividends ${}^{(3)}$ Cash dividends per share in CHF ${}^{(4)}$	2.36 2.34 1,968 1.05	2.03 2.00 1,724 1.00	1.88 1.84 1,367 0.95	$     \begin{array}{r}       1.49 \\       1.49 \\       1,268 \\       0.90     \end{array} $	1.46 1.46 1,259 0.85	1.30 1.30
Operating income from continuing operations per share: basic earnings per share in \$ <sup>(2)</sup> diluted earnings per share in \$ <sup>(2)</sup>	2.67 2.66	2.38 2.35	2.02 1.98	1.68 1.68	1.79 1.79	1.53 1.53

(1) Financial data presented on a continuing basis, excluding the results of the Agribusiness Division, which was spun-off in 2000.

(2) Basic and Diluted earnings and cash dividends per share have been adjusted to reflect a forty-for-one share split effective May 7, 2001. The year 2000 has been adjusted to take this split into account, in order to provide per share information on a consistent basis.

<sup>(3)</sup> Cash dividends represent cash payments in the applicable year that generally relate to earnings of the previous year.

(4) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2004 will be proposed to the Annual General Meeting on March 1, 2005 for approval.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
		(\$ millions,	except per	share data)	
BALANCE SHEET DATA Amounts in accordance with IFRS:					
Cash, cash equivalents and current marketable securities.	14,593	13,259	12,542	13,193	12,659
Inventories	3,558	3,346	2,963	2,449	2,515
Other current assets	6,460	5,668	5,310	4,712	4,923
Long-term assets	29,858	27,044	24,210	19,408	15,410
Total assets	54,469	49,317	45,025	39,762	35,507
Trade accounts payable	2,020	1,665	1,266	1,077	971
Other current liabilities	9,058	7,655	7,006	7,378	6,131
Long-term liabilities and minority interests	9,608	9,568	8,484	6,146	5,914
Total equity	33,783	30,429	28,269	25,161	22,491
Total liabilities and equity	54,469	49,317	45,025	39,762	35,507
Net assets	33,921	30,519	28,355	25,223	22,538
Outstanding share capital	881	896	898	925	946
Amounts in accordance with US GAAP: Income statement data					
Net income	4,989	3,788	3,829	2,419	3,794
Basic earnings per share <sup>(1)</sup>	2.12	1.59	1.58	0.98	1.51
Diluted earnings per share <sup>(1)</sup>	2.11	1.57	1.55	0.98	1.50
Balance sheet data					
Total equity	38,101	34,878	33,225	30,208	29,840
Total assets	59,281	55,748	50,361	45,105	43,976

(1) Earnings per share have been adjusted to reflect a forty-for-one share split effective May 7, 2001. 2000 figures have been adjusted to take this split into account, in order to provide earnings per share information on a consistent basis.

#### **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 <sup>(1)</sup> per share	Total Dividend per ADS
		(CHF)	(\$)
2000	April 2001	0.85	0.43
2001	March 2002	0.90	0.54
2002	March 2003	0.95	0.68
2003	February 2004	1.00	0.80
$2004^{(2)(3)}$	March 2005	1.05	0.93

<sup>(1)</sup> 2000 figures have been adjusted for a forty-for-one share split and share-to-ADS ratio change on May 7, 2001.

(2) If the Swiss franc amount for 2004 is translated into US dollars at the rate of \$0.88 to the Swiss franc, the Total Dividend per share and Total Dividend per ADS in US dollars would be \$0.93. 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.

<sup>(3)</sup> Dividend to be proposed at the Annual General Meeting on March 1, 2005.

#### **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 25, 2005, as found on Reuters Market System, was CHF 1.00 = \$0.84.

Year ended December 31,	Period End	Average <sup>(1)</sup>	Low	High
2000	0.61	0.59	0.55	0.65
2001	0.60	0.59	0.55	0.63
2002	0.71	0.65	0.58	0.72
2003	0.80	0.75	0.70	0.81
2004	0.88	0.81	0.76	0.88
Month end,				
August 2004			0.78	0.81
September 2004			0.79	0.80
October 2004			0.79	0.83
November 2004			0.83	0.88
December 2004			0.86	0.88
January 2005 <sup>(2)</sup>			0.84	0.88

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

<sup>(2)</sup> The high and low US dollar/Swiss franc exchange rate is current as of January 25, 2005.

#### 3.B Capitalization and Indebtedness

Not applicable.

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

Not applicable.

#### **3.D Risk Factors**

You should carefully consider all of the information set forth in this Form 20-F and the following risk factors which we face and which are faced by our industry. The risks below are not the only ones we face. Additional risks not currently known to us or that we presently deem immaterial may also impair our business operations. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This Form 20-F also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere. See "Forward-Looking Statements" on page 1.

#### **Risks Faced By Our Pharmaceuticals Division**

#### We face intense competition from new products.

Our products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, our competitors' products may be safer or more effective or more effectively marketed and sold than our products. Alternately, in the case of generic competition, they may be equally safe and effective products which are sold at a substantially lower price than our products. As a result, if we fail to maintain our competitive position, this could have a material adverse effect on our business and results of operations.

#### Our research and development efforts may not succeed.

Like other major pharmaceutical companies, in order to remain competitive, we must continue to launch new and better products each year. 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. Our ongoing investments in new product launches, new technologies and research and development for future products could produce higher costs without a proportional increase in revenues.

In the pharmaceutical business, the research and development process can take up to 12 years, or even longer, from discovery to commercial product launch. This process is conducted in various stages. During each stage there is a substantial risk that we will encounter serious obstacles or will not achieve our goals and accordingly we may abandon a product in which we have invested substantial amounts of time and money. If we are unable to maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient to cover our substantial research and development costs and to replace sales that are lost as older products approach the end of their commercial life cycles or are displaced by competing products or therapies, this could have a material adverse effect on our business and results of operations.

Our dependence on research and development makes it highly important that we recruit and retain high quality researchers and development specialists. We commit substantial efforts and funds to this purpose. Should we fail in our efforts, this could have a material adverse effect on our business and results of operations.

#### We face intense competition from lower-cost generic products.

Our Pharmaceuticals Division also faces increasing competition from lower-cost generic products. Our Pharmaceuticals Division's products are generally protected by patent rights which are expected to provide us with exclusive marketing rights. However, those patent rights are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the US or the EU. Even in the US and the EU, political pressures to reduce spending on prescription drugs has led to legislation which encourages the approval of generic products. As a result, although it is our policy to actively protect our patent rights, generic challenges to our products can arise at any time, and we may not be able to prevent the emergence of generic competition for our products.

Loss of patent protection for a product typically leads to a rapid loss of sales for that product and could affect our future results. In addition, proposals emerge from time to time in the US and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on our sales.

Patent protection is at issue in major markets for the following of our Pharmaceuticals Division's leading products.

- Neoral. Patent protection exists for the Neoral micro-emulsion formulation and other cyclosporin formulations through 2009 and beyond in major markets. Despite this protection, generic cyclosporin products competing with Neoral have entered the transplantation market segment in the US, Germany, Japan, Canada and elsewhere. We have filed patent infringement actions against manufacturers of these generic products. However, except in one lawsuit in Canada, we have so far not succeeded in obtaining an injunction against any of the manufacturers we have sued.
- Sandostatin. Basic patent protection for the active ingredient in Sandostatin SC has expired in the US, Japan, Germany and the UK, and it will expire in 2006 in France and 2007 in Italy. Several parties have filed applications to market generic versions of Sandostatin SC in the US. We have not, so far, sued any for patent infringement. However, patent protection extending to 2010 (and 2013 and beyond in the US) continues in major markets for Sandostatin LAR, a long-acting version of Sandostatin, which represents a significant and growing proportion of our sales in this product family.
- Lotrel/Cibacen/Lotensin/Cibadrex. The basic benazepril substance patent protection for Cibacen/ Lotensin/Cibadrex has expired in the US and Japan, and will expire in 2005-08 in major markets in the EU. However, Lotrel, which is a combination of benazepril and amlodipine besylate, is patented in the US until 2017. Teva and Dr. Reddy's Laboratories have challenged this patent. Dr. Reddy's is seeking marketing approval for a different benazepril combination, using amlodipine maleate, rather than amlodipine besylate. Because of this difference, the Dr. Reddy's product, if brought to market, would not be automatically substitutable in the US for Lotrel. However, Teva is seeking marketing approval for the same benazepril combination as Lotrel, and is thus seeking to bring a fully substitutable product to the US market. We have sued Teva and Dr. Reddy's in the US for patent infringement. The Dr. Reddy's case is currently stayed.
- Lamisil. The active ingredient in Lamisil is covered generically, but not mentioned specifically, in a patent family which has expired. Another patent family specifically discloses and covers the active ingredient specifically and expires in the US in 2006, and 2005-07 in Japan and major EU countries. The specific US patent had been challenged by Dr. Reddy Laboratories in the US. Dr. Reddy's has since withdrawn its suit and conceded that this patent is valid and enforceable.
- Miacalcin/Miacalcic. The specific Novartis formulation of this product is covered by patents which
  will expire in the US in 2015. However, patents on the Novartis formulation have expired in a
  number of other major countries, and will expire in Italy in 2006. Apotex has applied to the FDA
  for the right to sell a generic version of *Miacalcin*, using the Novartis formulation. We have sued
  Apotex for infringement. Two other companies have applied to the FDA for the right to sell a
  generic version of *Miacalcin* based on a different formulation. We have not sued these companies.
- *Exelon*. The active ingredient in *Exelon* is covered by a compound patent (granted to Proterra, AG and licensed to us), which presently expires in 2007, and has been determined by the FDA to qualify for patent term extension until 2012. In addition, we hold an isomer patent on *Exelon* which expires in 2014. Dr. Reddy's, Sun Pharmaceuticals and Watson Pharmaceuticals have filed

applications to market a generic version of *Exelon* in the US. Together with Proterra, we have sued all three parties for patent infringement.

- Focalin. The active ingredient in Focalin is covered by patents (granted to Celgene Corporation and licensed to us) through 2015 in the US and 2018 in other markets. Teva has challenged these patents and has filed an application for a generic version of Focalin in the US. Together with Celgene, we have sued Teva for patent infringement.
- *Trileptal*. Patent protection for *Trileptal*'s active ingredient has expired in major countries. In the US, New Chemical Entity data exclusivity under the Hatch-Waxman Act of 1984 is currently scheduled to expire in January 2005. However, we have applied for a six-month extension of this exclusivity period under the Hatch-Waxman pediatric exclusivity provisions. At the same time, we have pending patent filings relating to our marketed formulations of *Trileptal*, which, if granted, would expire in 2018 in major countries, including the US.
- *Starlix.* The active ingredient in *Starlix* is covered by Ajinomoto patents. The basic US patent will expire in 2006, but a request to extend the term of the patent until 2009 has been filed. In late January 2005 a third party informed us that they have filed an ANDA application to market a generic version of *Starlix* in the US. We are assessing that information and will respond appropriately.
- *Foradil*. Patent protection for *Foradil*'s active ingredient has expired in major countries. In the US, Hatch-Waxman data exclusivity is currently scheduled to expire in February 2006.
- *Voltaren*. *Voltaren* is off-patent. As a result, revenue from *Voltaren* has declined, and may decline significantly further over the next few years.

#### Price controls and other pressures may prevent us from setting prices for our products at levels high enough to earn an adequate return on our investments in them.

In addition to normal price competition in the marketplace, the prices of our Pharmaceutical Division's products are restricted by price controls and other pricing pressures imposed by governments and health care providers in most countries. Price controls operate differently in different countries and can cause wide variations in prices between markets. Currency fluctuations can aggravate these differences. The existence of price controls and other pricing pressures can limit the revenues we earn from our products and may have an adverse effect on our business and results of operations.

- United States. In the US, ongoing political debates over prescription drug pricing and recent Medicare reform legislation could increase pricing pressures. In particular, recent Medicare reform legislation is expected to lead to the creation of a new voluntary drug benefit for patients who are eligible for Medicare, and may require us to extend price discounts to more patients when the benefit goes into effect in 2006. In addition, there is continuing political pressure to amend this legislation to enable the US government to use its enormous purchasing power to demand discounts from pharmaceutical companies. It is not yet possible to predict with certainty the extent to which this recently-enacted legislation will affect our business and results of operations.
- *Europe*. In Europe, our operations are subject to significant price and marketing regulations. Many governments are introducing health care reforms in a further attempt to curb increasing health care costs.
- Japan. In Japan, the government generally introduces price cut rounds every other year, during which the government mandates price decreases for specific products.
- *Regulations favoring generics*. In response to rising healthcare costs, many governments and private medical care providers, such as Health Maintenance Organizations (HMOs), have instituted reimbursement schemes that favor the substitution of generic pharmaceuticals for more expensive brand-name pharmaceuticals. In the US, generic substitution statutes have been enacted

by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug instead of an original branded drug. We expect that the pressure for generic substitution will increase as a result of the implementation of the Medicare prescription drug benefit in 2006.

• *Cross-Border Sales.* Price controls in one country can also have an impact in other countries as a result of cross-border sales. In the EU, products which we have sold to customers in countries with stringent price controls can legally be re-sold to customers in other EU countries with less stringent price controls, at a lower price than the price at which the product is otherwise available in the importing country. This risk could increase due to the addition of 10 nations to the EU in 2004. In North America, products which we have sold to customers in Canada, which has relatively stringent price controls, are sometimes re-sold into the US, again at a lower price than the price at which the product is otherwise sold in the US. Such imports from Canada to the US are currently illegal. However, there are ongoing political efforts at the federal, state and local levels to change the legal status of such imports.

We expect that pressures on pricing will continue and may increase. Because of these pressures, there can be no certainty that in every instance we will be able to charge prices for a product that, in a particular country or in the aggregate, enable us to earn an adequate return on our investment in that product.

#### Public pressure on the pharmaceuticals industry could affect our business and results of operations.

There is considerable public sentiment against the pharmaceuticals industry, and the industry is under the close scrutiny of the public and the media. In addition there is significant pressure on our industry from certain disadvantaged nations to make our products available to their people at drastically lower costs. Any increase in such negative public sentiment or increase in public scrutiny or pressure from such disadvantaged nations could lead, among other things, to changes in legislation, to changes in the demand for our products, additional pricing pressures with respect to our products, or increased efforts to undercut intellectual property protections. Such changes could affect our business and results of operations.

#### **Risks Faced By Sandoz (Generics)**

# The success of Sandoz depends on our ability to successfully develop and commercialize additional generic pharmaceutical products.

To a significant degree, the future results of Sandoz depend upon our ability to successfully commercialize additional generic pharmaceutical products. We must develop new generic products, and prove that they are the bio-equivalent of the originator products. Once developed, we must successfully manufacture and bring these new products to market. The development and commercialization process is both lengthy and costly and involves a high degree of risk. Our products currently under development may not be approved by regulatory authorities, or may not be approved as quickly as expected. In addition, we may not be able to successfully and profitably produce and market such products. Delays in any part of the process or our inability to obtain regulatory approval of our products could adversely affect our operating results by restricting or delaying our introduction of new products. The continuous introduction of new generic products is critical to our business. (Sandoz has been a separate Division since January 1, 2005. Before that Sandoz was a Business Unit of our Consumer Health Division.)

## Our revenues and profits from any particular generic pharmaceutical products decline as our competitors introduce their own generic equivalents.

Selling prices of generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition for that product intensifies. To the extent that we succeed in being the first to bring to market a generic version of a significant product, our sales and our profits can be substantially increased in the period following the introduction of such product and prior to

a competitor's introduction of an equivalent product. Our ability to sustain our sales and profitability on any product over time is dependent on both the number of new competitors for such product and the timing of their approvals. The overall profitability of Sandoz depends, among other things, on our ability to to be the first to bring significant new products to market. There can be no guarantee that we will achieve this goal in the future.

## Our generic pharmaceutical products face intense competition from brand-name companies that sell or license their own generic products or successfully extend their market exclusivity period.

Competition in the generic pharmaceutical market continues to intensify as the pharmaceutical industry adjusts to increased pressures to contain health care costs. Brand-name companies have taken aggressive steps to counter the growth of the generics industry. In particular, brand-name companies continue to sell their products to the generic market directly by acquiring or forming strategic alliances with generic pharmaceutical companies. No significant regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. In addition, brand-name companies continually seek new ways to delay generic introduction and to decrease the impact of generic competition. These efforts by the brand-name pharmaceutical industry have had, and likely will continue to have, a negative effect on the results of operations of Sandoz.

## Recent changes in the US regulatory environment may prevent us from utilizing the exclusivity periods that are important to the success of our generic products.

Under US law the FDA must award 180 days of market exclusivity to the first generic manufacturer who challenges the patent of a branded product. However, recent changes in the Hatch-Waxman Act may affect the availability of this market exclusivity in the future. The new amendments now require generic applicants to launch their products within certain time frames or risk losing the marketing exclusivity that they had gained through being a first-to-file applicant.

# Sandoz's success may depend on its ability to successfully challenge patent rights held by branded pharmaceutical companies.

At times we seek approval to market generic products before the expiration of patents held by others for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by our products. As a result, we often face significant patent litigation. If we are unsuccessful in such litigation, then our ability to launch new products will be substantially limited. In addition, depending upon a complex analysis of a variety of legal and commercial factors, we may, in certain circumstances, elect to market a generic product even though litigation is still pending. This could be before any court decision or while an appeal of a lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages if the final court decision is adverse to us.

#### **Risks Faced By The Entire Novartis Group**

#### Government regulation may adversely affect our business.

Like our competitors, we are subject to strict government controls on the development, manufacture, marketing, labeling, distribution and pricing of our products. We must obtain and maintain regulatory approval for our pharmaceutical and many of our other products from regulatory agencies in order to sell our products in a particular jurisdiction.

*Risks regarding the development of new products.* Our research and development activities are heavily regulated. If we fail to comply fully with applicable regulations, then there could be a delay in the submission or approval of potential new products for marketing approval. In addition, the submission of an application to a regulatory authority does not guarantee that a license to market the product will be granted. Each authority may impose its own requirements and delay or refuse to grant approval, even when a product has already been approved in another country. In our principal markets, the approval

process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. This registration process increases the cost to us of developing new products and increases the risk that we will not succeed in selling them successfully.

*Risks regarding the manufacture of our products.* 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, 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.

*Risks regarding the marketing of our products.* The marketing of our products is also heavily regulated by governments throughout the world. In many countries, particularly those in Europe, we are prohibited from marketing many of our products directly to consumers. In the US, some direct-to-consumer marketing practices are permitted, but the scope of allowable marketing practices is still significantly limited. Most countries also place restrictions on the manner and scope of permissible marketing to physicians and other health professionals. The effect of such regulations may be to limit the amount of revenue which we may be able to derive from a particular product. In addition, if we fail to comply fully with such regulations then civil or criminal actions could be brought against us.

*Risks regarding the safety and efficacy of our products.* Regulatory agencies may at any time reassess the safety and efficacy of our products based on new scientific knowledge or other factors. Such reassessments could result in the amendment or withdrawal of existing approvals to market our products, which in turn would result in a loss of revenue, and could serve as an inducement to bring lawsuits against us.

Other regulatory and legal risks. Changes in worldwide intellectual property protections and remedies, trade regulations and procedures, product counterfeiting, unstable governments and legal systems, intergovernmental disputes and possible nationalizations could also materially adversely affect our business or results of operations.

#### We operate in highly competitive and rapidly consolidating industries.

We operate in highly competitive and rapidly consolidating industries. Our principal competitors are major international corporations with substantial resources for research and development, production and marketing. Our competitors are consolidating, and the strength of combined companies could affect our competitive position in all of our business areas.

#### Product liability claims could adversely affect our business and results of operations.

Product liability claims are potentially a significant commercial risk for us. Substantial damage awards have been made in some jurisdictions against companies such as ours based upon claims for injuries allegedly caused by the use of their products. We are involved in a number of product liability cases claiming damages as a result of the use of our products. See "Item 8. Financial Information—8.A Consolidated Statements and Other Financial Information—8.A.7 Legal Proceedings." We maintain product liability insurance policies with third parties, covering claims on a worldwide basis, and we believe that our insurance coverage and provisions are reasonable and prudent in light of our business and the risks to which we are subject. However, because other pharmaceutical companies have faced large product liability losses, third party product liability insurance coverage is becoming increasingly difficult to obtain. As a result, claims may occur which in whole or in part, might not be covered by third party insurance or the provisions that we have put in place. While no such losses are presently expected, there can be no guarantee that we will not also face a loss which far exceeds available insurance and provisions.

#### Patent claims by third parties could adversely affect our business and results of operations.

We take all reasonable steps to ensure that our products do not infringe valid third-party intellectual property rights. Nevertheless, third parties may assert claims against us for infringement. As a result, we can become involved in extensive litigation regarding our products. If we are unsuccessful in defending ourselves against these suits, we could be subject to injunctions preventing us from selling our products, or to damages, which may be substantial. Either event could have a material adverse effect on our consolidated financial position, results of operations or liquidity.

#### Our business will continue to expose us to risks of environmental liabilities.

In our product development programs and manufacturing processes, it is sometimes necessary for us to use hazardous materials, chemicals, biologics, viruses and toxic compounds. These programs and processes expose us to risks of accidental contamination, events of noncompliance with environmental laws and regulatory enforcement, personal injury, property damage and claims resulting from these events. If an accident occurred, or if we discover contamination caused by prior operations, we could be liable for clean-up obligations, damages or fines, which could have an adverse effect on our business and results of operations.

The environmental laws of many jurisdictions impose actual and potential obligations on us to remediate contaminated sites. These obligations may relate to sites:

- that we acquire, own or operate;
- that we formerly owned or operated; or
- where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. In particular, our financial accruals for these obligations may be insufficient if the assumptions underlying the accruals—including our assumptions regarding the portion of the waste at a site for which we are responsible—prove incorrect, or if we are held responsible for additional contamination.

Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to us, and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby harming our business and operating results.

# The manufacture of our products is technically highly complex, and a supply interruption or delay could adversely affect our business and results of operations.

The products we market, distribute and sell are either manufactured at our own dedicated manufacturing facilities, or through toll manufacturing arrangements or supply agreements with third parties. Since many of our products are the result of technically complex manufacturing processes, and are sometimes dependent on highly specialized raw materials, we can provide no assurances that supply sources will not be interrupted from time to time. In addition, for these same reasons, the volume of production of any product cannot be rapidly altered. As a result, if we should fail to accurately predict market demand for any of our products then we may not be able to produce enough of the product to meet that demand, or may produce too much of the product, either of which could affect our business and operating results.

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

A significant portion of our earnings and expenditures are in currencies other than US dollars, our reporting currency. In 2004, 43% of our sales were made in US dollars, 26% in Euro, 8% in Japanese yen, 3% in Swiss francs and 20% in other currencies. In 2004, 37% of our costs were generated in US dollars,

23% in Euro, 15% in Swiss francs, 5% in Japanese yen and 20% in other currencies. Changes in exchange rates between the US dollar and other currencies can result in increases or decreases in our costs and earnings. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured and the components of shareholders' equity. We seek to minimize our currency exposure by engaging in hedging transactions where we deem it appropriate. To mitigate some of these risks, we may hedge certain foreign currency positions for 2005. We cannot predict, however, all changes in currency and interest rates, inflation or other factors, which could affect our international businesses.

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

Our American Depositary Shares (ADSs) trade on the New York Stock Exchange in US dollars. Since the shares underlying the ADSs are listed in Switzerland on the SWX Swiss Exchange (SWX) and trade on the European trading platform virt-x in Swiss francs, the value of the ADSs may be affected by fluctuations in the US dollar/Swiss franc exchange rate. If the value of the Swiss franc decreases against the US dollar, the price at which our ADSs trade may decrease. 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 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 SWX. 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, as amended, is effective with respect to such rights and the related shares, or an exemption from the registration requirements thereunder is available. We would evaluate at the time of any share offering the costs and potential liabilities associated with any such registration statement, as well as the indirect benefits of enabling the exercise by the holders of ADSs of the preemptive rights associated with the shares underlying their ADSs, and any other factors we would consider appropriate at the time, and then would make a decision as to whether to file such a registration statement. We cannot guarantee that any 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 such holder's preemptive rights and distribute the net proceeds of the sale to the holder. If the depositary determines, in its discretion, that such 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 allows rights to lapse, holders of ADSs would not realize any value from the granting of preemptive rights.

#### Decreases in financial income could affect our earnings.

In recent years, we have earned a level of net financial income that exceeds our benchmarks in a difficult investment environment. We have accomplished this primarily through effective currency management and investment strategies. Given the volatile nature of investment markets, there can be no guarantee that this performance will be repeated in the future, or that we can avoid suffering losses from our management of our financial assets.

#### Changes in accounting rules could affect our reported results.

The International Accounting Standards Board has and will continue to critically examine current International Financial Reporting Standards (IFRS) with a view toward increasing international harmonization of accounting rules. This process of amendment and convergence of worldwide accounting rules resulted in significant amendments to the existing rules as of January 1, 2005 in such areas as the accounting for share-based compensation, goodwill and intangibles, marketable securities and derivative financial instruments, and the classification of certain income statement and balance sheet positions. These amendments are discussed in more detail in note 32m(xii) to the consolidated financial statements.

#### Changes in tax laws could adversely affect our earnings.

Changes in the tax laws of Switzerland, the US, or other countries in which we do significant business, as well as changes in our effective tax rate for the fiscal year caused by other factors, including changes in the interpretation of tax law by local tax officials, could affect our net income. While certain changes were enacted to the tax laws of major countries during 2004, those changes are not expected to materially impact our net income. It is not possible to predict the impact on our results of any tax legislation which may be enacted in the future.

#### Earthquakes could affect our business and results of operations.

Our corporate headquarters and certain of our major Pharmaceutical Division production facilities are located near major earthquake fault lines in Basel, Switzerland. In the event of a major earthquake, we could experience business interruptions, destruction of facilities and/or loss of life, all of which could materially adversely affect us.

#### Changes in global economic conditions and politics could affect our business and results of operations.

Our future results could be affected by global economic and political changes. In the recent past, terrorist attacks have had an impact on global economic conditions. Any additional terrorist attacks which may occur in the future, and any related military activity around the world, could have a similar impact, which could affect our business and results of operations.

#### Item 4. Information on the Company

#### 4.A History and Development of Novartis

Novartis is a world leader in the research, development, manufacturing and marketing of products to protect and improve health and well-being. Our goal is to discover, develop and successfully market innovative products to cure diseases, to ease suffering and to enhance quality of life. We also seek to provide a return to shareholders that reflects our performance and to adequately reward those who invest ideas and resources in our company.

In 2004, Novartis generated consolidated net sales of \$28.2 billion, invested \$4.2 billion in research and development and employed approximately 81,400 people worldwide through its activities in more than 140 countries.

Created in 1996 through the merger of Ciba-Geigy and Sandoz, up to December 31, 2004 Novartis was organized into two Divisions:

- · Pharmaceuticals, which comprises our activities in innovation-driven prescription medicines; and
- Consumer Health, which comprises our activities in Sandoz generic drugs, Over-the-Counter (OTC) self-medication products, animal health, medical nutrition, infant & baby foods, and lens and vision care.

As of January 1, 2005 Sandoz, which comprises our activities in generic drugs, became a separate Division. It was part of the Consumer Health Division until December 31, 2004.

Our name, derived from the Latin *novae artes*, means "new skills" and reflects our commitment to focus on research and development to bring new health-care products to the patients and physicians that we serve.

Ranked by IMS Health (IMS) as one of the fastest-growing global pharmaceutical companies worldwide in recent years, we are seeking to further expand our market share by introducing new products and maximizing sales. We have received approvals for 13 new products in the US since 2000. We are making renewed investments in research and development, particularly in the Novartis Institutes for BioMedical Research headquarters in Cambridge, Massachusetts.

Novartis is the only major pharmaceutical company with a global leadership position in both patented and generic pharmaceuticals. In light of the aging populations of many major countries, and the associated rise in health care expenditures, we believe generics will continue to play an increasingly important role as a cost-effective therapeutic option. Our objective is to strengthen our position as a medicines company, offering a broad range of drug treatment options to patients, physicians and payors, including:

- · Innovative, patent-protected prescription medicines that address significant unmet medical needs;
- Cost-effective and high-quality generic medicines of growing importance to health-care systems today; and
- Leading self-medication (OTC) brands to enhance overall health and well-being.

Our Pharmaceuticals Division has a portfolio of products that is balanced between products marketed to specialists and products which are marketed to primary care physicians. In 2004, a total of 5 products received regulatory approvals in major markets.

We intend to continue supporting and accelerating the development of new products in our pipeline, which has a total of 10 projects in clinical development or in registration procedures.

A total of 52 projects are in late-stage clinical development (Phase II, Phase III and registration), with a particular focus on a group of ten priority compounds, many of which have the potential to address urgent unmet medical needs and be first-in-class medicines in their respective therapeutic areas.

Novartis AG, headquartered in Basel, Switzerland, is a public company incorporated under the laws of Switzerland with an indefinite duration. 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

Our registered shares are listed in Switzerland on the SWX Swiss Exchange ("SWX") and traded on the European trading platform virt-x. Our American Depositary Shares are listed on the New York Stock Exchange ("NYSE"). Our shares are also traded on International Retail Service (IRS) at the London Stock Exchange. In the US, Corporation Service Company (2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, telephone: 1-800-927-9800) acts as our agent solely for the purpose of accepting service of process in respect of registration statements on Forms F-3 under the US Securities Act of 1933, as amended.

Major Corporate Developments 2002-2004

2004	
January	A new CHF 3.0 billion share repurchase program is announced to start following completion of a program initiated in 2002. Shareholders at the Annual General Meeting (AGM) approved the program in February 2004, and it commenced in August 2004.
February	The global adult medical nutrition business of Mead Johnson & Company, a Bristol-Myers Squibb Company subsidiary is acquired for approximately \$385 million in cash.
April	Novartis studies making a bid for a potential business combination with the French-German pharmaceutical group Aventis SA at the request of the Aventis Supervisory Board, but declines to make a bid.
June	Novartis announces plans to acquire two generics companies: the Danish company Durascan A/S from AstraZeneca plc and Sabex Holdings Ltd of Canada. Durascan expands our generics presence in the Nordic region, while Sabex, which was acquired for \$565 million in cash, provides strong growth opportunities in injectable generics and new entry into the Canadian generics sector.
July	Novartis Institute for Tropical Disease opens its new facility in Singapore with particular focus on biomedical research for dengue fever and drug-resistant tuberculosis (TB).
October	Novartis announces the reorganization of its Sandoz generics business. Effective January 1, 2005, Sandoz ceases to be a Business Unit of our Consumer Health Division, and becomes a separate Division.
2003	
February	US rights to market the tension headache products <i>Fioricet</i> and <i>Fiorinal</i> are sold to Watson Pharmaceuticals, Inc. for \$178 million.
April	An anti-incontinence product called <i>Enablex</i> in certain countries and <i>Emselex</i> in other countries is acquired from Pfizer Inc. We will pay up to \$225 million for the rights to this product. Part of that amount is contingent on obtaining approval in the US (approved in December 2004) and EU (approved in October 2004).
May	A majority ownership interest is acquired in Idenix Pharmaceuticals, Inc., for an initial payment of \$255 million in cash, with up to an additional \$357 million in future contingent payments to the selling stockholders if Idenix achieves certain future targets. We also obtained options to license future products from Idenix. In each case, we may pay additional amounts to Idenix in the event the applicable drug achieves certain future targets. In July 2004, Idenix completed an initial public offering (IPO) of its shares, and Novartis retained its existing 57% stake.
June	Novartis groups all of its generic pharmaceutical companies under the brand name Sandoz as part of a worldwide initiative to unite its generic pharmaceutical operations.
November	Novartis confirms its support for the Universal Declaration of Human Rights and announces new corporate human rights guidelines to meet its public commitments under the UN Global Compact.

January Two US farm animal vaccine companies, Grand Laboratories Inc., of Iowa, and ImmTech Biologies Inc., of Kansas, are acquired for a combined minimum purchase price of \$99 million, of which \$78 million was settled in Novartis American Depositary Shares. The final price may increase depending on whether certain future sales and other targets are met.
November Our Food & Beverage business is sold to Associated British Foods plc for \$270 million in cash. The remaining Health Food & Slimming and Sports Nutrition businesses were reorganized as a stand-alone unit, Nutrition & Santé, which for external reporting purposes has been consolidated into the Consumer Health Division's Medical Nutrition Business Unit. Sandoz acquires more than 99% of Lek Pharmaceuticals d.d., the Slovenian generics company, for \$0.9 billion in cash. In 2003, Lek was delisted from the Ljubljana Stock Exchange and Sandoz acquired its remaining outstanding shares.

#### 4.B Business Overview

Novartis is a world leader in both patent-protected and generic pharmaceuticals as well as consumer health products. Our aim is to seek and maintain leadership positions in these businesses.

Our company was organized into two Divisions up to December 31, 2004: Pharmaceuticals and Consumer Health.

The Pharmaceuticals Division is organized into two marketing organizations—Primary Care and Specialty Medicines—that develop and market branded pharmaceutical products in seven therapeutic areas. It also includes the Novartis Institutes for BioMedical Research (NIBR) which was established in 2003 with the aim of redefining drug discovery in a new era marked by the completion of the human genome sequence. NIBR is headquartered in Cambridge, Massachusetts, and has affiliates worldwide.

In 2004, the Consumer Health Division had six Business Units, all of which coordinate the worldwide research, development, manufacturing and marketing of their respective products. The Business Units are: Sandoz (generics), OTC self-medication, Animal Health, Medical Nutrition, Infant & Baby and CIBA Vision. As of January 1, 2005, Sandoz became a separate Division and will no longer be incorporated in the Consumer Health Division.

Sandoz is organized as a Retail Generics company which also operates two other businesses, Industrial Products and Biopharmaceuticals. The Retail Generics business produces finished dosage forms, which are sold to pharmacies, hospitals and other health care outlets. The Industrial Products business manufactures active pharmaceutical ingredients and their intermediates for internal requirements and industrial customers. The Biopharmaceuticals business, drawing on the company's rich experience in biotechnology, is developing to meet growing demand.

2002

### Key Figures

	Year Ended December 31,		
	2004	2003	2002
		(in \$ millions)	
Net Sales to third parties			
Pharmaceuticals	18,497	16,020	13,528
Sandoz	3,045	2,906	1,817
OTC	1,975	1,772	1,521
Animal Health	756	682	623
Medical Nutrition	1,121	815	711
Infant & Baby	1,441	1,361	1,333
CIBA Vision	1,412	1,308	1,135
Consumer Health—ongoing	9,750	8,844	7,140
Divested Health & Functional Food activities	, 		209
Consumer Health	9,750	8,844	7,349
Group net sales	28,247	24,864	20,877
Operating income			
Pharmaceuticals	5,253	4,423	3,891
Sandoz	235	473	265
OTC	351	309	240
Animal Health	78	88	92
Medical Nutrition	32	82	4
Infant & Baby	274	254	227
CIBA Vision	236	153	118
Divisional Management	(25)	(39)	
Consumer Health—ongoing	1,181	1,320	946
Divested Health & Functional Food activities			140
Consumer Health	1,181	1,320	1,086
Corporate income, net	105	146	115
Group operating income	6,539	5,889	5,092

The table below sets forth a regional breakdown of certain data for the years ended December 31, 2004, 2003 and 2002.

	Americas		Europe			Asia/Africa/Australia			
	2004	2003	2002	2004	2003	2002	2004	2003	2002
		(in	\$ milli	ons, exc	ept nun	ber of o	employe	es)	
Net sales	13,285	12,036	10,558	10,289	8,788	6,832	4,673	4,040	3,487
Operating income	1,417	897	958	4,625	4,505	3,825	497	487	309
Number of employees (at									
December 31)	30,186	28,608	28,328	38,229	37,510	32,595	12,977	12,423	11,954
Investment in property, plant and									
equipment	340	427	537	787	846	498	142	56	33
Depreciation of property, plant									
and equipment	229	220	198	510	480	355	41	37	39
Net operating assets	6,702	5,984	6,312	18,230	16,271	14,086	1,251	975	965

#### PHARMACEUTICALS

#### Overview

Our Pharmaceuticals Division, which is made up of approximately 80 affiliated companies and 47,325 employees and sells to approximately 140 countries, offers a broad portfolio of branded prescription medicines focused on treating the unmet medical needs of patients worldwide. In 2004, the Division reported consolidated net sales of \$18.5 billion, which represented 65% of total Group net sales.

The Pharmaceuticals Division develops and markets products in the following therapeutic areas:

#### Primary Care

- Cardiovascular & Metabolism
- Neuroscience
- Respiratory & Dermatology
- ABGHI (Arthritis, bone, gastrointestinal, hormone replacement therapy, infectious diseases)

#### Specialty Medicines

- Oncology & Hematology
- Transplantation & Immunology
- Ophthalmics

Our Pharmaceutical Division's current product portfolio includes more than 40 key marketed products, many of which are their respective market leaders. In addition, the Division's portfolio of development projects includes more than 75 potential new products and potential new indications or formulations for existing products in various stages of clinical development.

### Selected Key Marketed Products

The following table describes selected key marketed pharmaceutical products, in alphabetical order, by therapeutic area. Not all products are registered in all markets for all of the indications described below.

Therapeutic Area	Compound	Generic name	Indication	Formulation
PRIMARY CARE Cardiovascular & Metabolism	Diovan HCT/ Co-Diovan	valsartan and hydrochlorothiazide	Hypertension	Film-coated tablet
	Diovan	valsartan	Hypertension Heart failure in patients intolerant of ACE inhibitors Post-myocardial infarction	Capsule Coated tablet
	Lescol/ Lescol XL	fluvastatin sodium	Primary hypercholesterolemia and mixed dyslipidemia Secondary prevention of coronary events Slowing the progression of atherosclerosis Increase of high-density lipoprotein cholesterol (HDL-C)	Capsule Tablet
	Lotensin/ Cibacen	benazepril hydrochloride	Hypertension	Coated tablet
	Lotensin HCT/ Cibadrex	benazepril hydrochloride and hydrochlorothiazide	Hypertension Adjunct therapy in heart failure Progressive chronic renal insufficiency	Coated tablet
	Lotrel	amlodipine besylate and benazepril hydrochloride	Hypertension	Capsule
	Starlix	nateglinide	Type 2 diabetes	Coated tablet

Therapeutic Area	Compound	Generic name	Indication	Formulation
Neuroscience	Comtan	entacapone	Parkinson's disease	Coated tablet
	Exelon	rivastigmine tartrate	Alzheimer's disease	Capsule Oral solution
	Focalin	dexmethylphenidate HCl	Attention-deficit hyperactivity disorder	Tablet
	Clozaril/ Leponex	clozapine	Treatment-resistant schizophrenia Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and schizoaffective disorder	Tablet
	Ritalin/ Ritalin LA	methylphenidate HCl	Attention-deficit hyperactivity disorder	Tablet Capsule
	Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease	Coated tablet
	Tegretol	carbamazepine	Epilepsy Acute mania and bipolar affective disorders Treatment of pain associated with trigeminal neuralgia	Tablet Chewable tablet Syrup Suppository
	Trileptal	oxcarbazepine	Epilepsy, including pediatric monotherapy	Tablet Oral suspension
Respiratory & Dermatology	Elidel	pimecrolimus cream	Atopic dermatitis (eczema)	Cream
	Foradil	formoterol	Asthma Chronic obstructive pulmonary disease	Aerolizer (capsules) Aerosol
	Lamisil	terbinafine	Fungal infections of the skin and nails	Tablet Cream DermGel Solution Spray
	Xolair	omalizumab	Allergic asthma	Subcutaneous injection

Therapeutic Area	Compound	Generic name	Indication	Formulation
ABGHI (Arthritis, Bone, Gastrointestinal disease, Hormone replacement therapy and Infectious diseases)	Enablex/ Emselex	darifenacin hydrobromide	Overactive bladder	Tablet
	Famvir	famciclovir	Acute herpes zoster Recurrent genital herpes in immunocompetent patients Recurrent mucocutaneous herpes simplex infections in HIV- infected patients	Tablet
	Zelnorm/ Zelmac	tegaserod	Irritable bowel syndrome with constipation Chronic constipation	Tablet
	Coartem/ Riamet	artemether and lumefantrine	Treatment of <i>Plasmodium falciparum</i> malaria or mixed infections that include <i>Plasmodium falciparum</i> Standby emergency malaria treatment	Tablet
	Combipatch/ Estalis	estradiol norethisterone acetate	Symptoms of estrogen deficiency in post-menopausal women Post-menopausal osteoporosis	Patch
	Estraderm/ Estraderm MX	estradiol	Symptoms of estrogen deficiency in post-menopausal women Post-menopausal osteoporosis	Patch
	Estragest TTS	estradiol norethisterone acetate	Symptoms of estrogen deficiency in post-menopausal women Post-menopausal osteoporosis	Patch

Therapeutic Area	Compound	Generic name	Indication	Formulation
	Miacalcin/ Miacalcic	salmon calcitonin	Osteoporosis Paget's disease Hypercalcemia	Nasal spray Ampoule Vial
	Vivelle-Dot/ Estradot	estradiol	Symptoms of estrogen deficiency in post-menopausal women Post-menopausal osteoporosis	Patch
	Voltaren	diclofenac	Inflammatory forms of rheumatism Pain management	Coated tablet Drop Ampoule Suppository Gel
SPECIALTY				
MEDICINES Oncology & Hematology	Femara	letrozole tablets/ letrozole	Advanced post-menopausal breast cancer (worldwide) Extended adjuvant use in early breast cancer following tamoxifen	Coated tablet
	Gleevec/ Glivec	imatinib mesylate/ imatinib	Certain forms of Chronic myeloid leukemia (CML) Certain forms of gastrointestinal stromal tumors (GIST)	Tablet Capsule
	Sandostatin LAR/ Sandostatin SC	octreotide acetate for injectable suspension/ octreotide acetate	Acromegaly Symptoms associated with functional gastroenteropancreatic endocrine tumors	Vial Ampoule Pre-filled syringe
	Zometa	zoledronic acid for injection/zoledronic acid	Hypercalcemia of malignancy Prevention of skeletal-related events in patients with bone metastases from solid tumors	Liquid concentrate Vial

Therapeutic Area	Compound	Generic name	Indication	Formulation
Transplantation & Immunology	Certican	everolimus	Prevention of organ rejection following heart or kidney transplantation	Tablet Tablet for oral suspension
	Myfortic	mycophenolic acid	Prevention of graft rejection following kidney transplantation	Enteric coated tablet
	Neoral	cyclosporine, USP modified	Prevention of graft rejection following organ and bone marrow transplantation Severe psoriasis Rheumatoid arthritis	Capsule Oral solution
	Simulect	basiliximab	Acute organ rejection in de novo renal transplantation Atopic dermatitis (eczema) Uveitis Nephrotic syndrome	Vial
Ophthalmics	Visudyne	verteporfin	Age-related macular degeneration (all forms of wet AMD)	Vial, activated by laser light
	Zaditor/ Zaditen	ketotifen	Allergic conjunctivitis	Eye drops

#### **Compounds in Development**

The following table describes some of our compounds and new indications for our existing products presently under development. "Submission" means that product registration documents have been submitted to the FDA, to regulatory authorities in the EU (by either the centralized or mutual recognition procedure) and/or to national health authorities in Europe, but not necessarily in all jurisdictions.

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
PRIMARY CARE						
Cardiovascular & Metabolism	Diovan	valsartan	Heart failure in patients intolerant of ACE inhibitors (Val-HeFT)	Angiotensin-II receptor blocker	Oral	US (approved) EU (submitted) Approved in five markets
			Post-myocardial infarction (VALIANT)		Oral	US/EU (submitted) Approved in 22 markets
	Diovan and Starlix	valsartan and nateglinide	Prevention of new onset type 2 diabetes, cardiovascular morbidity and mortality (NAVIGATOR)		Oral	≥2007/III
	Lotrel	amlodipine besylate and benazepril hydrochloride	Hypertension (5-40 and 10-40)	ACE inhibitor and calcium channel blocker	Oral	US (Submitted)
			High-risk hypertension (ACCOMPLISH)		Oral	≥2007/III
	LAF237	vildagliptin	Type 2 diabetes	Dipeptidyl- pepidase (DPP-4) inhibitor	Oral	2006/III
	SPP100	aliskiren	Hypertension	Renin inhibitor	Oral	2006/III
	NKS104	pitavastatin	Dyslipidemia	HMG CoA reductase inhibitor	Oral	≥2007/II
	LBM642	TBD	Dyslipidemia	PPAR alpha and gamma dual agonist	TBD	≥2007/I
	FAD286	TBD	Congestive heart failure		TBD	TBD/I
	VNP489	TBD	Hypertension	NEP inhibitor	TBD	TBD/I

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
Neuroscience	Focalin XR	methylphenidate	Attention-deficit hyperactivity disorder	Dopamine transport blocker	Oral	US (submitted)
	Exelon TDS	rivastigmine tartrate	Alzheimer's disease	Cholinesterase inhibitor	Transdermal patch	2006/III
	Exelon	rivastigmine tartrate	Non Alzheimer's dementia	Cholinesterase inhibitor	Oral	2005/III
	Trileptal NP	oxycarbazepine	Neuropathic pain	Voltage sensitive sodium channel blocker	Oral	2007/III
	LIC477	licarbazepine	Bipolar disorder	Voltage sensitive sodium channel blocker	Oral	2007/III
	AMP397	TBD	Epilepsy	AMPA receptor antagonist	Oral	≥2007/II
	SAB378	TBD	Neuropathic pain	Cannabinoid-1 receptor agonist	Oral	≥2007/II
	FTY720	TBD	Multiple sclerosis	Sphingosine-1- phosphate receptor agonist	Oral	≥2007/II
	AEP924	TBD	Depression	Somatostatin receptor antagonist	TBD	≥2007/I
	XBD173	TBD	Generalized anxiety disorder	Mitochondrial benzodiazepine receptor agonist	Oral	≥2007/I

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
Respiratory & Dermatology	Foradil	formoterol	Multi-dose dry powder inhaler in asthma	Long-acting beta-2 agonist	Dry powder for inhalation	US/EU (submitted) Approved in five European countries
	Xolair	omalizumab	Allergic asthma	Anti-IgE monoclonal antibody	Sub- cutaneous	US (approved) EU (submitted)
			Peanut allergy	Anti-IgE monoclonal antibody	Sub- cutaneous	2007/I
			New formulations	Anti-IgE monoclonal antibody	Liquid formulation	2007/I
	Lamisil	terbinafine	Fungal infection of the scalp in children	Fungal squalene epoxidase inhibitor	Oral	2006 (US)/III
			Nail lacquer for fungal infection	Fungal squalene epoxidase inhibitor	Nail Lacquer	≥2007/I
	Elidel	pimecrolimus	Seborrheic dermatitis	T-cell and mast cell inhibitor	Cream	2006/II
			Atopic dermatitis	minortor		2006/III
			in infants Chronic hand dermatitis			2006/III
	Elidel Ointment	pimecrolimus	Inflammatory skin diseases	T-cell and mast cell inhibitor	Ointment	2006/II
	ASM981	pimecrolimus oral	Inflammatory skin diseases	T-cell and mast cell inhibitor	Oral	TBD/II
	QAB149	TBD	Asthma Chronic obstructive pulmonary disease	Once-daily beta-2 agonist	Inhalation	2007/II
	Foradil/ mometasone	Formoterol/ mometasone	Asthma Chronic obstructive pulmonary disease	Long-acting beta-2 agonist/inhaled corticosteroid	Inhalation	2007/I
	ACZ885	TBD	Asthma	Monoclonal antibody to IL-1 beta	TBD	2007/I
	VAG624	TBD	Acne	Steroid sulfatase inhibitor	TBD	TBD/I
	ABN912	TBD	Asthma	Monoclonal antibody to monocyte chemoattractant protein-1	TBD	≥2007/I
	QAN747	TBD	Asthma Chronic obstructive pulmonary disease		TBD	≥2007/I
	QAE397	TBD	Asthma		TBD	≥2007/I
	QAK423	TBD	Asthma Chronic obstructive pulmonary disease		TBD	≥2007/I

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
ABGHI (Arthritis, Bone, Gastrointestinal diseases, Hormone replacement therapy, Infectious diseases)	Prexige	lumiracoxib	Osteoarthritis Acute pain Primary dysmenorrhea	Cyclo-oxygenase-2 inhibitor	Oral	UK (approved) EU (2005/III) US 2007/III
			Rheumatoid arthritis	Cyclo-oxygenase-2	Oral	EU 2006/III
			New formulations (oral suspension; parenteral)	inhibitor Cyclo-oxygenase-2 inhibitor	Oral	TBD/I
	Zelnorm/ Zelmac	tegaserod	Irritable bowel syndrome with constipation Dyspepsia Gastroesophageal reflux disease Chronic constipation in certain countries	5HT4-receptor agonist	Oral Solution	US (approved) EU (submitted) 2006/II 2007/II
	Aclasta	zoledronic acid	Paget's disease Osteoporosis Rheumatoid arthritis	Bisphosphonate, osteoclast inhibitor	Intravenous	US/EU (submitted) 2007/III ≥2007/II
	LTD600	telbivudine	Hepatitis B	Viral polymerase inhibitor	Oral	2005/III
	LDC300	valtorcitabine	Hepatitis B	Viral polymerase inhibitor	Oral	≥2007/II
	AAE581	balicatib	Osteoporosis	Cathepsin K inhibitor	Oral	≥2007/II
	SMC021	calcitonin	Osteoporosis	Regulator of calcium homeostasis	Oral	≥2007/II
	ACZ885	TBD	Rheumatoid arthritis	Monoclonal antibody to IL-1 beta	TBD	≥2007/I
	AKU517	TBD	Gastroesophageal reflux disease	Reversible acid pump antagonist	TBD	≥2007/I
	LBM415	TBD	Anti-bacterial	Peptide deformylase inhibitor	TBD	≥2007/I
	AFG495	TBD	Osteoporosis		TBD	TBD/I

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
SPECIALTY MEDICINES Oncology &	Zometa	zoledronic	Treatment of	Bisphosphonate	Intravenous	Japan
Hematolgy		acid	bone metastases	Displiosphonate	Intravenous	(submitted)
	Femara	letrozole	Breast cancer (extended adjuvant therapy)	Aromatase inhibitor	Oral	US (approved) EU (submitted)
			Breast cancer (early adjuvant therapy)	Aromatase inhibitor	Oral	2005/III
	ICL670	deferasirox	Chronic iron overload	Iron chelator	Oral	2005/III
	PTK787	vatalanib	Colorectal cancer Solid tumors	Angiogenesis inhibitor	Oral	2005/III TBD/I
	EPO906	patupilone	Solid tumors	Microtubule depolymerization inhibitor	Oral	2007/II
	OctreoTher	edotreotide	Somatostatin receptor-positive tumors	Radioactive labeled peptide	Intravenous	TBD/II
	PKC412	midostaurin	Acute myeloid leukemia (AML)	Signal transduction inhibitor	Oral	TBD/II
	SOM230	pasireotide	Acromegaly GEP neuroendocrine tumors	Somatostatin (sst) 1/2/3/5 binder and hormone inhibitor	injection	r 2006/II
	Gleevec/ Glivec	imatinib mesylate/ imatinib	Solid tumors	Signal transduction inhibitor	Oral	2007/II
	LBQ707	gimatecan	Solid tumors	Topoisomerase-I inhibitor (cytotoxic)	Oral	2007/II
	RAD001	everolimus	Solid tumors	Growth-factor- induced cell proliferation signal transduction inhibitor	Oral	≥2007/II
	AMN107	TBD	Chronic myeloid leukemia (CML)	Signal transduction inhibitor	Oral	2007/I
	LBH589	TBD	Solid and liquid tumors	Histone deacetylase inhibitor	Oral	2007/I
	AEE788	TBD	Solid tumors	Tyrosine kinase inhibitor	Oral	≥2007/I
	ABJ879	TBD	Solid tumors	Microtubule stabilizer	Intravenous injection	≥2007/I

Therapeutic area	Project/ Compound	Generic name	Indication	Mechanism of action	Formulation	Planned filing dates/Current phase
Transplantation & Immunology	Certican	everolimus	Prevention of organ rejection	Growth-factor- induced cell proliferation inhibitor	Oral	EU (approved) US (submitted)
	FTY720	TBD	Prevention of organ rejection	Sphingosine-1 -phosphate receptor agonist	Oral	2006/III
	AEB071	TBD	Prevention of organ rejection	T-cell activation Ophthalmics	TBD	TBD/I
Ophthalmics	Visudyne	verteporfin	Age-related macular degeneration (AMD)(occult)	Photosensitizer for photodynamic therapy	Intravenous	2005/III
	Sandostatin LAR	octreotide acetate	Diabetic retinopathy Other indications	Growth hormone and IGF-1 inhibitor	Intra muscular	2005/III
	Lucentis <sup>™</sup>	ranibizumab	Age-related macular degeneration (AMD)	VEGF blocker	Intra-vitreal	2005 (EU)/III
	Elidel	pimecrolimus	Dry eye Blepharitis	T-cell and mast cell inhibitor	Eye drops	≥2007/II ≈ ≥2007/II

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

**Phase II:** Clinical studies that test the safety and efficacy of the compound in patients with the targeted disease with the goal of determining the appropriate doses for further testing and evaluating study design as well as identifying common side effects and risks. (Cancer drugs, as well as those for other life-threatening diseases, can sometimes be submitted for approval based on only Phase II data).

**Phase III:** Large-scale clinical studies with several hundred or several thousand patients to establish safety and effectiveness for regulatory approval for indicated uses and to evaluate the overall benefit-risk relationship.

The tables shown above and the summary that follows describe key products and compounds in development in the Pharmaceuticals Division. Unless otherwise indicated, and subject to required regulatory approvals and, in certain instances, contractual limitations, we intend to sell our marketed products throughout the world. These same compounds are in various stages of development throughout the world. For some compounds, the development process is ahead in the US, for other compounds, development is behind in the US. Due to the uncertainties associated with the development process, and due to regulatory restrictions in some countries, including 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.

#### **Primary Care**

#### Cardiovascular & Metabolism

Novartis is a world leader in offering products to treat cardiovascular disease, particularly high blood pressure (hypertension), elevated cholesterol (hyperlipidemia) and heart failure. We believe that our broad portfolio of cardiovascular and metabolic agents offer some of the best tools available today to treat and protect patients along critical points of the cardiovascular continuum—from novel treatments for type 2 diabetes and medicines to manage hypertension and high cholesterol, to life-saving therapies following heart attack and for patients who are suffering from heart failure.

Our pipeline includes compounds with the potential to change the way cardiovascular and metabolic diseases are treated, in particular the oral DPP-4 inhibitor LAF237 (vildagliptin) for type 2 diabetes and the oral renin inhibitor SPP100 (aliskiren) for hypertension.

#### **Key Marketed Products**

- *Diovan* (valsartan) and *Co-Diovan/Diovan HCT* (valsartan and hydrochlorothiazide) are leaders in the angiotensin II receptor blocker (ARBs) class of anti-hypertensive (high-blood pressure) agents. The ARB drug class has been a key growth driver in the global anti-hypertensive market, with *Diovan* consistently ranking as the most prescribed brand in this class, according to IMS Health. *Diovan* specifically inhibits a hormone, angiotensin II, from binding to a receptor and causing arteries to tighten and narrow, an action that can cause high blood pressure. The fixed combination product *Co-Diovan*, which includes the diuretic hydrochlorotiazide, provides additional efficacy for patients who require a greater reduction in blood pressure than can be achieved with either agent alone. In the US, *Diovan* is approved for the treatment of hypertension as well as for congestive heart failure in patients who are intolerant of angiotensin converting enzyme (ACE) inhibitors, another class of anti-hypertensive agents. Besides the US, *Diovan* is available in more than 50 countries for the treatment of heart failure and in more than 80 for the treatment of hypertension. *Diovan* was first launched in 1996.
- Lescol/Lescol XL (fluvastatin sodium) is a statin lipid-lowering agent approved as an adjunct to diet for reducing elevated total cholesterol levels (hyperlipidemia) as well as to treat abnormal cholesterol levels (dyslipidemia) and to slow the progression of hardening of the arteries (atherosclerosis) in patients with coronary heart disease. Lescol was first launched in the UK in 1995 and it is also indicated for use in reducing the risk of undergoing coronary revascularization procedures in patients with coronary heart disease. Lescol XL is an extended-release formulation launched in 2000 to allow for once-daily dosing.
- Lotensin/Cibacen (benazepril) is an ACE inhibitor used to treat high blood pressure that was first launched in 1989 as Cibacen in some areas of the world and then in 1991 in the US under the trade name Lotensin. In addition, in certain countries this medicine is approved for use as an adjunct therapy in heart failure and for the treatment of chronic renal insufficiency, a kidney disorder. A fixed-combination product called Lotensin HCT/Cibadrex has been developed as a second-line high blood pressure therapy that combines benazepril hydrochloride with hydrochlorothiazide, a widely used diuretic. In January 2005, the Swedish specialty medicines company Meda acquired the rights to Cibacen and Cibadrex in most European markets for a cash payment of \$135 million.
- Lotrel (benazepril and amlodipine) is a fixed combination anti-hypertensive treatment consisting of the ACE inhibitor benazepril used in Lotensin/Cibacen and the leading calcium antagonist amlodipine. Launched in 1996 and only available in the US, Lotrel has been ranked by IMS Health as one of the leading prescribed branded combination anti-hypertensive therapies in the US since 2002.
- *Starlix* (nateglinide) is an oral blood-glucose lowering agent for use in patients with type 2 diabetes. The drug helps to control blood glucose levels at mealtime through a rapid onset of action for a short duration. Launched in both the US and EU in 2001, it is approved in the EU for use in combination therapy with metformin, another type of oral anti-diabetic agent. In the US, *Starlix* is approved as a monotherapy in patients initiating drug treatment and in combination with the oral anti-diabetic agents metformin or thiazolidinediones.

#### New Indications in Development

• *Diovan* (valsartan) has been approved for congestive heart failure in the US and in other global markets. Additionally, Novartis has filed for this indication in the EU based on the positive clinical benefits in heart failure in the large-scale VAL-HEFT trial. *Diovan* has also been filed in the US

and EU for use in the treatment of patients following a heart attack, known as "post-myocardial infarction," based on data from the VALIANT trial. To date, *Diovan* has been approved for this indication in over 22 countries. In addition, *Diovan* is in further development for prevention of new-onset type 2 diabetes and cardiovascular disease in patients with impaired glucose tolerance (IGT). *Diovan* is currently being investigated alone and in combination with *Starlix* (nateglinide) in the NAVIGATOR (Nateglinide and Valsartan in Impaired Glucose Tolerance and Outcomes Research) trial. At its conclusion, the trial will demonstrate whether *Diovan* and/or *Starlix* can reduce the incidence of cardiovascular disease events and prevent people with IGT from progressing to clinical diabetes. Results are expected to be available in 2008.

- *Starlix* (nateglinide) is currently being investigated in combination with *Diovan* as part of the NAVIGATOR trial.
- Lotrel (amlodipine besylate and benazepril hydrochloride) has two new dosages being developed for hypertension (Lotrel 5-40 and Lotrel 10-40). We received an "approvable" letter from the FDA for these new dosages, requesting additional data before the dosages can be approved. We are conducting further studies in order to develop that data, and expect the studies to be completed in the second quarter of 2005. In addition, more than 12,000 patients are being treated with Lotrel or with a combination of benazepril hydrochloride and the diuretic hydrochlorothiazide in the ACCOMPLISH trial that began in October 2003 to investigate cardiovascular morbidity and mortality in patients with high-risk hypertension

#### **Compounds in Development**

- LAF237 (vildagliptin) is an oral dipeptidyl peptidase (DPP)-4 inhibitor in Phase III development for the treatment of type 2 diabetes. The first in a novel class called incretin enhancers, vildagliptin increases levels of two specific incretin hormones found in the stomach—glucagon-like peptide (GLP)-1 and gastric inhibitory polypeptide (GIP)—by blocking the action of DPP-4, an enzyme that normally inactivates them. GLP-1 and GIP are secreted from the intestine in response to food and stimulate insulin production by the beta cells of the pancreas. GLP-1 also reduces the secretion of glucagon, a hormone that signals the liver to produce glucose. In this way, LAF237 helps to address the imbalance between insulin supply and demand, one of the underlying causes of type 2 diabetes. LAF237 is currently in Phase III development after Phase IIb studies showed it to be efficacious both as monotherapy and in combination with metformin as well as showing a good safety and tolerability profile. In addition, the combination of LAF237 and metformin showed good durability of efficacy over a one-year period compared to metformin alone. Phase III data are expected at the end of 2005. Submission is planned for early 2006.
- SPP100 (aliskiren) is the first in a new class of hypertension agents called renin inhibitors that offers a once-daily treatment with efficacy and safety comparable to angiotensin-receptor blockers (ARBs), another class of high blood pressure treatments. In contrast to other antihypertensive agents, SPP100 lowers renin enzyme activity in the bloodstream, so it may have the potential to better protect against heart attacks (myocardial infarction) and kidney disease. Phase IIb/III data confirmed efficacy as a monothereapy and suggested benefits of combination with ARBs. Phase III data are expected in Q3 2005. The first regulatory submission is planned for early 2006.
- NKS104 (pitavastatin) is a lipid-lowering agent in development for the treatment of elevated total cholesterol. Novartis has the European marketing rights under a licensing agreement from Kowa. Clinical trials have shown that NKS104 lowers "bad" LDL cholesterol and triglycerides while increasing "good" HDL cholesterol levels. It is currently in Phase II development.
- LBM642 is a preoxisome proliferator-activated receptor (PPAR) alpha and gamma dual agonist being developed for the treatment of abnormal cholesterol (dyslipidemia), diabetes and obesity. Triglyceride-lowering effects have been demonstrated in a Phase I trial, and additional Phase I trials are ongoing with respect to diabetes.

- FAD286 is a novel compound for the treatment of congestive heart failure, currently in Phase I trials.
- VNP489 is the combination of a novel inhibitor of the neutral endopeptidase and valsartan, now in Phase I trials for the treatment of hypertension.

#### Neuroscience

Novartis has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for a series of disorders that include Alzheimer's disease, Parkinson's disease, attention deficit/hyperactivity disorder, epilepsy, depression, schizophrenia and migraine.

Among our leading products are the anti-epileptic *Trileptal*, which has been used to treat over one million adults and children suffering from epilepsy, and *Exelon*, which was first approved in 1997 and is now available for the treatment of mild to moderate Alzheimer's disease in more than 70 countries.

Novartis continues to be active in the research and development of new compounds and is committed to addressing unmet medical needs as well as supporting patients and their families affected by these disorders. Ongoing research to extend the current product portfolio in Neuroscience includes projects in psychiatric diseases (bipolar disorder, psychosis, depression and anxiety), neurological disorders (Alzheimer's disease, multiple sclerosis, amyotrophic lateral sclerosis) and chronic pain.

#### **Key Marketed Products**

- *Clozaril/Leponex* (clozapine) remains a leading anti-psychotic for treatment-resistant schizophrenia. First launched in the 1970s and facing generic competition in the US and many other markets, this product is also indicated for the prevention of suicidal behavior in patients with schizophrenia or schizo-affective disorder.
- *Comtan* (entacapone) treats Parkinson's disease by enhancing the action of levodopa, the standard therapy for Parkinson's disease. The compound is licensed from Orion Pharma, which retains exclusive rights to market *Comtan* under a different brand name in certain European countries.
- *Exelon* (rivastigmine tartrate) is a symptomatic treatment of mild to moderate Alzheimer's disease dementia. It belongs to a class of drugs known as cholinesterase inhibitors (ChEI's) that increase neurotransmitter activity in the brain. It was approved for the treatment of Alzheimer's disease in 1997 and is currently used in over 70 countries with over 2.8 million patient years of treatment.
- *Focalin* (dexmethylphenidate HCl) is the single isomer version of methylphenidate and is approved in the US for the treatment of ADHD (attention deficit/hyperactivity disorder). This compound is licensed from Celgene Corporation.
- *Ritalin LA* (methylphenidate hydrochloride) is a once-daily formulation of *Ritalin* launched in 2002 for the treatment of attention-deficit hyperactivity disorder in both children and adults. This product, which removes the need for a midday dose, has been approved in a number of countries, including the US, EU and countries in Latin America.
- *Stalevo* (carbidopa, levodopa and entacapone) is an optimized levodopa product indicated for the treatment of Parkinson's disease patients with signs and symptoms of end-of-dose "wearing off." This product combines levodopa, considered the most effective treatment for Parkinson's disease, with the enzyme inhibitors carbidopa and entacapone. It has been shown to significantly improve the ability of patients with Parkinson's disease to perform everyday tasks and to reduce symptoms associated with the disease. Licensed from Orion Pharma, *Stalevo* was first launched in the US in 2003 and is now available in all major European markets. Orion retains exclusive rights to this product in certain Scandinavian countries, Germany, the UK and Ireland.
- *Tegretol XR/CR* (carbamazepine) is the long-acting formulation of *Tegretol*, which has long been a mainstay for the treatment of epileptic seizures and has faced generic competition for some time.

First launched in 1996, *Tegretol XR/CR* 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.

• *Trileptal* (oxcarbazepine) is an anti-epileptic drug for the treatment of partial seizures as adjunctive or monotherapy in both adults and children over age 4. It acts by stabilizing neuronal functions, thereby controlling and limiting the spread of seizures. First approved in Europe in 1999 and in the US in 2000, *Trileptal* can be used as a monotherapy in adults and children or in combination with other anti-epileptic medicines in adults.

#### New Indications in Development

- *Exelon* (rivastigmine tartrate) is in development for further indications like dementia associated with Parkinson's disease. In addition, a transdermal formulation called *Exelon TDS* is in Phase III development for Alzheimer's disease and aims to increase patient convenience and compliance due to improved tolerability of the therapy.
- *Focalin XR* (dexmethylphenidate HCl) is the single-isomer version of methylphenidate, the active ingredient in *Ritalin*. A long-acting formulation was submitted for US regulatory approval in July 2004 for the treatment of pediatric and adult attention-deficit hyperactivity disorder. This compound is licensed from Celgene. *Focalin XR* uses SODAS<sup>™</sup> technology, a proprietary drug delivery technology under license from Elan.
- *Exelon* (rivastigmine tartrate) is in development for additional indications and formulations. A transdermal formulation, *Exelon TDS*, is in Phase III for Alzheimer's disease, and is aimed at increasing patient convenience and compliance due to improved tolerability of the therapy.
- Trileptal NP (oxcarbazepine) is in Phase III for the treatment of neuropathic pain.
- *Trileptal* (oxcarbazepine) is being prepared for US and EU submission to extend the pediatric indication down to one month of age.

# **Compounds in Development**

- LIC477 (licarbazepine) is a sodium channel blocker. Phase III trials were initiated in 2004 for the treatment of acute manic episodes in bipolar disorders.
- AMP397 is an AMPA receptor antagonist in Phase II development for treating epilepsy.
- SAB378 is a cannabinoid-(CB)-1 receptor agonist in Phase II development for the treatment of neuropathic pain.
- FTY720, an oral immunomodulator with a novel mechanism of action, has shown significant efficacy in multiple sclerosis (MS) in a Phase II study. FTY720 has the potential to become the first efficacious oral therapy for MS, a condition estimated to affect more than one million people worldwide. Data from the Phase II study showed a significant reduction in the relapse rate and in the number of brain lesions detected by MRI scan as well as a longer time to first relapse. The vast majority of patients are continuing in the extension phase. One-year data are expected in mid-2005. Phase III studies are planned to start in mid-2005. FTY720 is licensed from Mitsubishi.
- AEP924 is a somastatin receptor antagonist in Phase I trials for the treatment of depression.
- XBD173 is a mitochondrial benzodiazepine ligand in Phase I trials for the treatment of anxiety.
- Iloperidone has been out-licensed to Vanda Pharmaceuticals, Inc., while AAG561 and TCH346 have been terminated.

#### **Respiratory & Dermatology**

Our current focus in dermatology is on the treatment of two very common diseases—the inflamed skin condition known as atopic dermatitis, or eczema, and fungal nail infections. Novartis offers a series of leading medicines for these conditions. *Elidel* is the first and only non-steroid cream for eczema, a disease that affects about 10% of children in the US, while *Lamisil* is the most frequently prescribed treatment worldwide for fungal nail infection.

Novartis also offers various therapies in the respiratory field, including the long-acting bronchodilator *Foradil* for the treatment of asthma and chronic obstructive pulmonary disease (COPD). In addition, we are developing *Xolair*, a novel biological therapy already approved in the US, Australia, New Zealand and Brazil that targets an underlying cause of allergic asthma.

## **Key Marketed Products**

- *Elidel* (pimecrolimus cream) is the first non-steroid cream approved for the treatment of atopic dermatitis, a skin condition commonly known as eczema, in adults and children. It is one of the first new eczema treatments introduced since the 1950s, when topical corticosteroids—historically the mainstay of therapy—became available. First launched in 2002 in the US, *Elidel* is now registered in approximately 90 countries, including many EU markets.
- Foradil (formoterol fumarate) is a long-acting bronchodilator that offers 5 minute onset of action and 12 hour relief of symptoms for patients with asthma and chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema. It was first approved and launched in Switzerland in 1994, followed by other key European markets in 1997. US approval was granted in 2001, and Novartis then licensed *Foradil* to Schering-Plough in 2002 in the US but continues to market and distribute the product in other areas of the world. *Foradil Aerolizer* is a single-dose dry powder inhaler, while a metered-dose inhaler is available in some countries. This product is licensed from Yamanouchi.
- Lamisil (terbinafine) is a leading therapy for onychomycosis, also known as fungal nail infection. Lamisil tablets kill the fungus that causes the infection at its source, working through the patient's bloodstream. This product was first launched in 1991 and is now available in more than 90 countries, with the US being the leading market. Lamisil tablets are also approved for treating athlete's foot (tinea pedis) and fungal infection of the scalp (tinea capitis) in some countries, though not yet in the US. Our Consumer Health Division's OTC Business Unit markets over-the-counter (OTC) cream formulations of Lamisil for use in treating athlete's foot in many markets, including the US.
- Xolair (omalizumab) is the first humanized therapeutic antibody for the treatment of allergic asthma and the first approved therapy designed to target the antibody IgE, a key underlying cause of the symptoms of allergic asthma. Xolair is the only asthma treatment dosed every two or four weeks and is administered by subcutaneous injection. In the US and Canada, Xolair is indicated for use in adults and children over age 12 with moderate-to-severe allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair, which gained US and Australian regulatory approval in 2003, is being jointly developed with Genentech and Tanox, and is co-marketed in the US by Novartis Pharmaceuticals Corporation and Genentech. Xolair has also been submitted for EU regulatory approval for the treatment of severe allergic asthma.

#### New Indications in Development

• *Foradil* (formoterol) has received an approvable letter in the US for the *Certihaler* formulation. The *Certihaler* is a novel, breath-activated multi-dose dry powder inhaler technology that was developed by SkyePharma, which will also manufacture the device. The *Certihaler* has a dose counter which is easy to read and also gives patients confirmation that the full dose has been administered. We licensed the exclusive US distribution and marketing rights for this product to Schering-Plough.

Product registration files for the *Foradil Certihaler* have also been submitted in Europe and the rest of the world, and regulatory approvals have been received in five European countries and Mexico. This replaces a prior agreement with Ivax to market *Foradil* with Ivax's Airmax<sup>®</sup> device, which has been discontinued. In 2002, we entered into a co-development and co-commercialization agreement with Schering-Plough to bring to market a fixed-dose combination *Foradil* product with the inhaled steroid mometasone. The Phase I/II program for the fixed-dose combination product is expected to start in 2005, and submission is planned for 2007.

- *Xolair* (omalizumab) is being studied in clinical trials in patients with peanut allergy and in children ages 6-12 with allergic asthma. A liquid formulation to improve patient convenience is also in development. This product is being jointly developed with Genentech and Tanox.
- *Lamisil* (terbinafine) is in Phase III development for ringworm of the scalp (tinea capitis). A new topical formulation (nail lacquer) is also in phase I for the treatment of fungal nail infections.
- *Elidel* (pimecrolimus) cream 1% is in Phase II development for seborrheic dermatitis and in Phase III development for atopic dermatitis in infants, chronic hand dermatitis and prophylactic treatment of severe atopic dermatitis.

# **Compounds in Development**

- QAB149 has the potential to be the first beta-2 agonist that offers true 24-hour control for the treatment of asthma and chronic obstructive pulmonary disease (COPD). This compound, which is currently in Phase II, has been shown to have a fast onset of action and proven efficacy for over 24 hours with once-daily dosing. It is expected to have an improved side-effect profile compared to current beta-2 agonists. We have entered into an agreement with SkyePharma to develop QAB149 using the *Certihaler* multi-dose dry powder inhalation device. Regulatory submissions are planned for 2007. Several options for combinations are currently being evaluated in parallel.
- ASM981 (pimecrolimus, the active component of Elidel cream) oral and ointment formulations are also in Phase II development for inflammatory skin diseases.
- ACZ885 is an inhibitor of IL-1 mediated eosinophilla and lung macrophage accumulation that is in Phase I development for the treatment of asthma and chronic obstructive pulmonary disease (COPD).
- VAG624 is a steroid sulphatase inhibitor in Phase I development for the treatment of acne.
- ABN912 is a fully human monoclonal antibody to Monocyte Chemoattractant Protein-1 in Phase I development for the treatment of asthma and chronic obstructive pulmonary disease (COPD).
- QAN747 is a novel compound in Phase I development for the treatment of asthma and chronic obstructive pulmonary disease (COPD).
- QAE397 is a novel compound for the treatment of asthma and chronic obstructive pulmonary disease (COPD).
- QAK423 is a novel compound in Phase I development for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

# Arthritis/Bone/Gastrointestinal/Hormone Replacement Therapy/Infectious Diseases (ABGHI)

The primary focus of this therapeutic area is on patients with a variety of internal diseases that have significant unmet medical needs, particularly in the areas of gastrointestinal disorders (including urinary incontinence), arthritis, osteoporosis, the treatment of pain and infectious diseases.

We have entered the gastrointestinal market with the launch of Zelnorm/Zelmac for the treatment of irritable bowel syndrome (IBS), a condition where the bowel (large intestine) does not function properly. More than 40 million Americans are estimated to suffer from IBS with constipation, and Zelnorm/Zelmac is the first and only medication approved to treat this condition. Zelnorm/Zelmac is also approved for the treatment of chronic idiopathic constipation in the US and several other countries. We intend to further strengthen our GI franchise with development efforts regarding the use of Zelnorm/Zelmac to treat upper gastrointestinal disorders such as dyspepsia, gastroesophageal reflux disease (GERD) and other conditions.

Another important area of focus are bone disorders like osteoporosis, a progressive disease that causes bones to become thin and porous, increasing the risk for fractures. Led by *Miacalcin/Miacalcic*, Novartis has a number of treatments in development for this disease, which is estimated to affect up to one in three women over age 50 worldwide, according to the International Osteoporosis Foundation. The most advanced compound in development for bone disorders is *Aclastsa*, which was submitted in the US for the treatment of Paget's disease in 2004 and is being studied for use in osteoporosis.

Our infectious diseases portfolio consists of three main areas: anti-virals, anti-bacterials and tropical medicine. We market *Famvir* for herpes and *Coartem* for malaria. Ongoing research and development efforts are focused on new specific anti-virals against Hepatitis B and C as well as on novel antibiotics for respiratory tract infections. We established Infectious Diseases as a separate franchise following our May 2003 purchase of a majority of the outstanding capital stock of Idenix Pharmaceuticals, Inc. As a result of that transaction, we obtained certain rights to market Idenix products as well as options to license additional Idenix compounds in the future.

# **Key Marketed Products**

- *Enablex/Emselex* (darifenacin) is a once-daily oral treatment that is part of a new group called M3-selective receptor antagonists for the treatment of overactive bladder. Known as Enablex in the US and Emselex in the EU, this product was approved in the EU in October 2004 and approved in the US in December 2004. *Enablex/Emselex* has been shown to effectively reduce the number of weekly incontinence episodes by up to 77% versus placebo. It was acquired from Pfizer in April 2003.
- *Famvir* (famciclovir) is an anti-viral agent for the treatment of recurrent genital herpes, a sexuallytransmitted, life-long disease, and shingles (herpes zoster), which is caused by the reactivation of the highly contagious variacella-zoster virus, the same virus that causes chickenpox. Other indications include the treatment of recurrent mucocutaneous herpes simplex infections in HIV-infected patients.
- Zelnorm/Zelmac (tegaserod) is the first in a new class of medicines known as serotonin-4 (5-HT4) receptor partial agonists approved for the short-term treatment of the multiple symptoms associated with irritable bowel syndrome with constipation (IBS-C) in women. This product, which is known as Zelnorm in North America and South Africa, and Zelmac in other markets, acts by decreasing the visceral sensitivity of the intestinal tract, increasing intestinal secretion and increasing gastro-intestinal motility. This reduces the impact of symptoms such as abdominal pain, bloating and constipation. In 2004, Zelnorm received US approval to become the first treatment approved for chronic idiopathic constipation in men and women under age 65. First launched in 2002, this product has now been approved in more than 30 countries and has been submitted for EU approval.
- *Coartem/Riamet* (artemether and lumefantrine) is an effective and well-tolerated anti-malarial treatment for adults and children that achieves cure rates of up to 95%, based on clinical trial data, even in malaria patients with multi-drug resistance. It is indicated for treatment of falciparum malaria, the most dangerous form of malaria. *Coartem* is the only fixed-dose combination of the two agents artemether, an artemisinin derivative, and lumefantrine, known as the Artemisinin

Combination Therapy (ACT). *Coartem*, which is also marketed commercially as *Riamet* in some countries, was co-developed by Novartis in collaboration with Chinese parties that supply some of the active ingredients (artemether) and is produced in China by Novartis. First approved in 1998, *Coartem* is currently registered in approximately 75 countries. Novartis has provided more than six million treatments at cost to the World Health Organization (WHO) as part of the Roll Back Malaria initiative since 2002. The WHO has added *Coartem* to its List of Essential Medicines, and Novartis is increasing production capacity to help meet a significant increase in demand for the ACT therapy.

- *Voltaren* (diclofenac sodium) is a leading non-steroidal anti-inflammatory drug (NSAID) for the treatment of inflammatory and degenerative forms of rheumatism, and in the treatment of pain and inflammation. This product, which faces generic competition, has a wide variety of ingestible dosage forms marketed by the Pharmaceuticals Division as well as a topical therapy offered as *Voltaren Emugel* in several markets for the treatment of inflammation of tendons, ligaments, muscles and joints as well as certain localized forms of rheumatism.
- *Miacalcin/Miacalcic* (salmon calcitonin) is an important treatment for bone metabolic diseases, especially for established post-menopausal osteoporosis in women. *Miacalcin/Miacalcic* was first launched as an injection in 1974 and as a nasal spray in 1986, and it was first launched as an injection in the US in 1989 and in 1995 in an intra-nasal form. It contains chemically synthesized salmon calcitonin, a thyroid hormone that regulates the calcium content in the blood. Available in the US in both injectable form and as a nasal spray, *Miacalcin/Miacalcic* is indicated for use in women with low bone mass more than five years after menopause who refuse or cannot tolerate estrogens or in whom estrogens are contraindicated. As injection, it is also indicated for the treatment of symptomatic Paget's disease, a chronic condition that causes the growth of abnormal bone, and for the treatment of hypercalcenia, when a rapid decrease in serum calcium is required.
- Combipatch/Estalis (estradiol & norethindrone acetate transdermal system) is a combination estrogen/progestin treatment for symptoms of estrogen deficiency in post-menopausal women, and the prevention of post-menopausal osteoporosis. The product offers a convenient treatment in a single patch for patients with an intact uterus. *Combipatch* is not approved in the US for the prevention of post-menopausal osteoporosis. This product is sublicensed from Aventis for sale in countries outside the US and Japan under the brand name *Estalis*. In the US, the product is licensed by Noven Pharmaceuticals to Vivelle Ventures, which is a joint venture between Noven and our US affiliate, for sale under the brand name *Combipatch*.
- *Estraderm* and *Estraderm MX* (estradiol transdermal system) are estrogen-only treatments for symptoms of estrogen deficiency in post-menopausal women, and prevention of post-menopausal osteoporosis. These are earlier generations of transdermal patches.
- *Estragest TTS* (estradiol & norethindrone acetate transdermal system) is a low-dose combination estrogen/progestin treatment for symptoms of estrogen deficiency in post-menopausal women, and prevention of post-menopausal osteoporosis. *Estragest TTS* is an earlier generation of transdermal patches. *Estragest TTS* offers a high amenorrhea rate in a single patch for patients with an intact uterus. This product is not approved in the US.
- Vivelle-Dot/Estradot (estradiol transdermal system), licensed from Noven Pharmaceuticals is an
  estrogen-only treatment for symptoms of estrogen deficiency in post-menopausal women, and
  prevention of post-menopausal osteoporosis. Vivelle-Dot/Estradot is the smallest estrogen patch
  available and offers a thin, flexible and discreet hormone therapy. The lowest dose of Vivelle-Dot/
  Estradot (0.025 mg/d) is approved for the prevention of post-menopausal osteoporosis.

# New Indications in Development

• Zelnorm/Zelmac (tegaserod maleate/tegaserod) has been submitted for EU approval for the treatment of irritable bowel syndrome with constipation in women. In addition, Zelnorm/Zelmac is

under development for the treatment of various upper gastro-intestinal tract disorders, such as severe upset stomach (dyspepsia), which is in Phase III, and gastroesophageal reflux disease (GERD), which is in Phase II.

Aclasta (zoledronic acid) is a bisphosphonate being developed for the treatment of various benign metabolic bone diseases, including osteoporosis and Paget's disease. Aclasta was submitted for US and EU regulatory approval in 2004 for the treatment of Paget's disease following positive Phase III trial results. The product name is subject to regulatory approval, as well. On January 20, 2005, the EU's Committee for Medicinal Products for Human Use (CHMP) recommended that the European Commission grant a Marketing Authorization for Aclasta for the treatment of Paget's disease in all 25 EU countries plus Norway and Iceland. A Phase II trial in post-menopausal osteoporosis patients demonstrated that zoledronic acid, administered as a once-yearly infusion, induced sustained reduction in bone resorption and significant increases in bone mineral density at different skeletal sites. Phase III trials in different osteoporosis, corticosteroid-induced osteoporosis, prevention of recurrent clinical fracture after acute hip fracture) are currently in progress. Zoledronic acid at a different dosing regimen is marketed for oncology indications under the brand name Zometa.

# **Compounds in Development**

- Prexige (lumiracoxib) is a COX-2 inhibitor that was submitted for US and UK regulatory approval as well as to several other health authorities for the treatment of osteoarthritis, rheumatoid arthritis and acute pain, including painful menstrual cramps (primary dysmenorrhea). Prexige received its first regulatory approval in Mexico in March 2003 for all indications, followed by approvals in Australia, Brazil, Ukraine, New Zealand and several Latin American countries. Approval of the osteoarthritis and acute pain indications was obtained in the UK in September 2003, and the Mutual Recognition Procedure (MRP) in the EU was started in September 2004. We received a non-approvable letter in the US in September 2003. The FDA requested the submission of the final report of the TARGET study as well as additional clinical data for the indications of osteoarthritis and acute pain. In TARGET, lumiracoxib at two or four times the recommended daily dose for treating osteoarthritis showed a 79% reduction in serious upper gastrointestinal ulcer complications compared to NSAIDs (naproxen 500mg twice daily and ibuprofen 800 mg three times daily). There was no significant difference in cardiovascular safety compared to NSAIDs, and no significant difference in the frequency of serious hepatic adverse events. These findings were published in The Lancet. In November 2004, we temporarily withdrew Prexige from the MRP due to the European Medicines Agency's (EMEA) ongoing review of the cardiovascular safety of COX-2 inhibitors, which had been triggered by Merck's withdrawal of Vioxx® from the market. We expect to resume the MRP in mid-2005 after the EMEA completes this review. In the US, discussions are underway with the FDA on requirements for a new cardiovascular safety study. Additional studies are already underway to support the 100 mg dose for treating osteoarthritis. However, submission for US approval is not expected before 2007.
- LDT600 (telbivudine) and LDC300 (*valtorcitabine*) are currently in development for the treatment of hepatitis B. We have licensed these compounds from Idenix, a company in which we own a majority of the issued stock. We have the right to co-promote or co-market these compounds with Idenix in the US, the UK, France, Germany, Italy and Spain, and to market these compounds on our own in the rest of the world. These compounds are currently in Phase III and Phase II clinical trials, respectively. In addition to the license to these hepatitis B compounds, Idenix also granted us an option to license all other compounds developed by Idenix, including Idenix's hepatitis C drug candidate, NMC283, which is currently in Phase I clinical trials.
- AAE581 is a compound with a novel mode of action for the treatment of osteoporosis that is currently in Phase II development. It is a specific inhibitor of osteoclast-derived cathepsin K, which

leads to reduced collagen breakdown and osteoclast-mediated bone resorption. AAE581 has been shown to effectively suppress biological markers of bone turnover for up to 28 days in healthy volunteers and for up to three months in healthy post-menopausal women compared to placebo.

- SMC021 (calcitonin) is an oral formulation of salmon calcitonin, the active ingredient in *Miacalic/Miacalcin*, used in the treatment of osteoporosis. This compound, a novel concept in oral peptide delivery, is currently in Phase II development for the treatment of osteoporosis.
- ACZ885 is a human monoclonal antibody directed against human IL-1-beta that is in Phase I development for the treatment of rheumatoid arthritis and respiratory diseases.
- AKU517 is a reversible acid pump antagonist which is in Phase I development in collaboration with Sankyo for the treatment of gastroesophageal reflux disease (GERD), also known as heartburn.
- LBM415 is a new mode of action antibiotic known as a peptide deformylase inhibitor currently in Phase I development for respiratory tract infections.
- AFG495 is a novel compound for the treatment of osteoporosis currently in Phase I trials.
- RGN303 and RAD001 (rheumatoid arthritis) have been terminated.

# **Specialty Medicines**

# **Oncology & Hematology**

Oncology & Hematology provides a range of innovative therapies and practical solutions for cancer patients. We market products for the treatment of a number of different cancers and for cancer complications, including advanced malignancies involving bone. Research and development in this disease area is aimed at the discovery and development of innovative approaches to the treatment of cancer.

Novartis ranks No. 3 worldwide in the global oncology market with a 9.1% market share as of October 2004, according to IMS Health.

Key products include *Gleevec/Glivec*, to treat certain forms of life-threatening gastrointestinal stromal tumors (GIST) and chronic myeloid leukemia (CML), *Femara*, a leading treatment in certain types of breast cancer, and *Zometa*, a novel treatment for certain cancers that have spread to the bones. Important compounds in development include PTK787, an angiogenesis inhibitor initially being studied for the treatment of colorectal cancer, and the iron chelator ICL670 for use in patients suffering from chronic iron overload.

#### **Key Marketed Products**

• *Femara* (letrozole) is an oral aromatase inhibitor for the treatment of certain forms of breast cancer. It works by inhibiting the synthesis of estrogen, a hormone that promotes the growth of some breast cancers. *Femara* received US approval in October 2004 as an extended adjuvant (post-surgery) therapy treatment for early breast cancer in post-menopausal women who have received adjuvant tamoxifen therapy for five years. Use in this setting has also been approved in Switzerland, the UK, Mexico and other countries, and EU approval is expected in early 2005. Data from the landmark MA-17 study presented at the American Society of Clinical Oncology, which was the basis for this new indication. The new labeling for this indication reflects data showing an overall reduced risk of recurrence (38%) and a reduction in distant recurrences (distant metastases) of 39%. *Femara* was first launched in 1996, and it has since then received approval as a first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer, treatment of advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy, and neo-adjuvant (pre-operative) therapy. *Femara* is currently available in more than 80 countries worldwide.

- Gleevec/Glivec (imatinib mesylate/imatinib) is a signal transduction inhibitor approved to treat certain forms of leukemia and gastrointestinal stromal tumors. It is one of the first oncology drugs that validates rational drug design based on an understanding of how some cancer cells work. A signal transduction inhibitor interferes with the pathways that stimulate the growth of tumor cells. In the US, Gleevec (known outside the US as Glivec), is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of chronic myeloid leukemia (CML). This condition is a rare form of cancer but one of the most common adult leukemias, and it usually tests positive for the presence of the Philadelphia (Ph) chromosome. Gleevec/Glivec is also indicated for the treatment of patients with certain forms of gastrointestinal stromal tumors (GIST). Gleevec/Glivec, which is also being studied in solid tumors, was first launched in 2001 and is now available in more than 80 countries. The Glivec International Patient Assistance Program is now available in 71 countries and has provided treatment at no charge to more than 10,000 patients worldwide who otherwise would not have access to this innovative therapy.
- Sandostatin SC/Sandostatin LAR (octreotide acetate) is primarily used for the treatment of patients with acromegaly, a chronic disease in adults caused by over-secretion of pituitary growth hormone. Complications associated with acromegaly include cardiovascular disease, respiratory distress such as upper airways obstruction, malignancies such as colon cancer, and carbohydrate intolerance, which can lead to diabetes. Sandostatin is a synthetic protein that mimics the action of somatostatin, a naturally occurring hormone. This product is also indicated for the treatment of certain symptoms associated with pancreatic and gastrointestinal endocrine tumors. Sandostatin SC, which was launched in the US in 1988, is subject to near-term patent expirations. However, patent protection for Sandostatin LAR, which represents a significant and growing proportion of our octreotide sales, continues in major markets. See "—Intellectual Property" for further information. Sandostatin LAR is a long-acting release formulation that requires administration once every 28 days and has been approved for the control of symptoms such as the severe diarrhea associated with metastatic carcinoid tumors and the severe diarrhea associated with vasoactive intestinal polypeptide secreting tumors.
- Zometa (zoledronic acid) is a treatment for certain cancers that have spread to the bones that is used most often along with other cancer treatments, such as radiation, hormonal therapy or chemotherapy. Zometa, a third-generation bisphosphonate, is approved in most key markets for the treatment of hypercalcemia of malignancy, which means tumor-induced excessive levels of calcium, as well as the treatment of skeletal-related events in patients with cancer types such as prostate, breast, lung and multiple myeloma that have spread to involve bone.

#### **New Indications in Development**

- Zometa (zoledronic acid) has been submitted for regulatory approval in Japan for the treatment of bone metastases, an indication approved in the US and EU in 2001.
- *Femara* (letrozole) has been submitted for extended adjuvant breast cancer treatment in the EU based on the MA-17 study and is in Phase III development for use in the early adjuvant treatment setting. This Phase III study, called BIG 1-98, involves nearly 8,000 post-menopausal women with early breast cancer and will compare the utility of four different treatment paradigms of *Femara* compared to the anti-estrogen agent tamoxifen. This trial is ongoing and initial safety and efficacy results are expected to be presented by early 2005. Submission for regulatory approval is expected in 2005 for the Femara vs. tamoxifen arms, and data from the sequential arms of the study are expected in 2008.

• *Gleevec/Glivec* (imatinib mesylate/imatinib) is being studied as a potential treatment of solid tumors primarily as part of a combination therapy. Preclinical data have shown that *Gleevec/Glivec* enhances the effect of chemotherapy in animal models. Phase II trials are in progress in the following cancers: hormone-refractory prostate cancer, KIT-positive acute myeloid leukemia (AML), glioblastoma multiforme and as an adjuvant use in treating refractory gastrointestinal stromal tumors (GIST).

# **Compounds in Development**

- ICL670 (deferasirox) is an oral iron chelator in Phase III development to reduce excess iron in the blood. Iron accumulation resulting from repeated blood transfusions, particularly for patients with thalassemia (an inherited genetic defect that damages red blood cells and requires frequent blood transfusions) and sickle cell disease, can lead to organ damage and death. ICL670 has been shown in clinical trials to efficiently induce iron excretion and has the potential to become the first significant breakthrough therapy for this condition in more than 40 years, replacing the need for patients to undergo 12-hour infusions for five to seven days per week. Submissions for US and EU regulatory approval are expected in the first half of 2005.
- PTK787 (vatalanib) is a new molecular entity called an angiogenesis inhibitor that blocks all known vascular endothelial growth factors (VEGF). Two Phase III studies—CONFIRM 1 and CONFIRM 2—are evaluating this compound in patients with colorectal cancer compared to and in combination with the FOLFOX4 chemotherapy regimen, which is the combination of oxaliplatin, fluorouracil and leucovorin. PTK787 has been shown to be generally well tolerated based on experience in treating more than 1,000 patients. This compound is being developed in collaboration with, and, if approved, will be marketed jointly with Schering AG of Germany.
- EPO906 (patupilone), a cytotoxic, is a novel tubulin polymerizingcompound known as an epothilone that inhibits cancer cells with a similar mechanism as paclitaxel, a taxane that has been a member of one of the most successful class of anti-cancer treatments. EPO906 has shown more potency than paclitaxel in pre-clinical trials and more activity in paclitaxel-resistant tumors in pre-clinical trials. Responses have been observed in Phase II in several solid tumors. Dose-limiting toxicity, diarrhea, and significant myelosuppression has not been reported to date. This compound is currently in Phase II development.
- *OctreoTher* (edetreotide) is an intravenous peptide hormone analogue in Phase II development for the treatment of solid tumors. It carries a radioactive element specific to receptor-positive malignant cells containing the hormone somatostatin.
- PKC412 (midostaurin) is a protein kinase inhibitor (FLT3 inhibitor) in Phase II development for the treatment of acute myeloid leukemia (AML). Pilot studies have shown biological activity in more than 70% of patients with FLT3 mutations who were treated with PKC412 as a single agent therapy. Studies are investigating PKC412 in combination with chemotherapy to determine if responses of longer duration can be achieved.
- SOM230 is a somatostatin analog in Phase II development for the treatment of acromegaly; Cushing's syndrome, a rare disorder in which body tissue is exposed to excess levels of the stress hormone cortisol; and gastro-entero-pancreatic (GEP) tumors.
- LBQ707 (gimatecan) is a cytotoxic in Phase II development for the treatment of solid tumors. This compound, which has been licensed from Sigma-Tau, is a novel oral topoisomerase I inhibitor. Preclinical data have shown greater potency than topotecan or irinotecan as well as activity in cell lines resistant to these two anti-cancer agents. Confirmed partial responses have been seen in Phase I studies in non-small cell lung cancer, breast cancer and colorectal cancer.
- RAD001 (everolimus) is an mTOR pathway inhibitor in Phase II for the treatment of solid tumors. RAD001 is a novel macrolide being developed as an anti-proliferative drug through its inhibition of

the mTOR protein kinase, making it an attractive candidate for a broad range of cancer indications.

- AMN107 is a highly potent signal transduction inhibitor being studied for patients with a form of chronic myeloid leukemia (CML) resistant to *Gleevc/Glivec*, the standard of care. AMN107, like *Gleevec*, binds to the BCR-ABL protein that causes white blood cells to grow and divide uncontrollably. AMN107 has been shown to be the most selective BCR-ABL inhibitor to date and more potent that *Gleevec*. Phase I/II data showed hematological responses of over 50% in *Gleevec*resistant patients in advanced disease stages (accelerated or blast phase). Phase II trials are expected to begin in the first half of 2005.
- LBH589 is a histone deacetylase inhibitor in Phase I development for the treatment of solid tumors.
- AEE788 is a tyrosine kinase protein inhibitor that targets EGFR, HER2 and VEGFR2 that is in phase I development for the treatment of solid tumors.
- ABJ879 is a microtubule stabilizer in Phase I development for the treatment of solid tumors.
- Development of LAQ824 and XAA296 have been terminated.

# Transplantation & Immunology

Novartis is a world leader in transplantation and immunology, pioneering and revolutionizing the field of transplantation with the discovery and introduction of cyclosporine more than 20 years ago. We have one of the broadest portfolios of immunosuppressant due to our continued research and strong commitment to provide solutions to unmet medical needs for the transplant recipient. *Neoral* and *Simulect* are established products used to protect transplanted organs from rejection. Our new products are *Certican* and *myfortic*, which has now been approved in more than 40 countries, are providing more choices to transplant physicians. A novel immunomodulating agent, FTY720, is currently in Phase III for use in transplantation, and patient enrollment was completed in September 2004. With a worldwide research program, Transplantation & Immunology is committed to developing a new and innovative range of therapeutic products for the prophylaxis of organ rejection and to maintain our role as a global leader in this field.

# **Key Marketed Products**

- Neoral (cyclosporine, USP modified) is a micro-emulsion formulation of cyclosporine, an immunosuppressant used in both adults and children to prevent organ rejection following a kidney, liver or heart transplant. According to IMS Health, Neoral is the world's most commonly used primary immunosuppressant after largely replacing its predecessor Sandimmun/Sandimmune, which was introduced in 1982 and revolutionized organ transplantation. First launched in 1995, Neoral was designed to provide improved and constant absorption. It is also used in treating severe autoimmune disorders such as psoriasis and rheumatoid arthritis. Despite our patent protection for Neoral, generic companies have launched competing products in the US, Europe and elsewhere, and will continue to compete vigorously. See "—Intellectual Property" for further information.
- *Certican* (everolimus) is a new immunosuppressant drug called a "proliferation signal inhibitor" (or motor inhibitor) that targets the primary causes of allograft dysfunction (also known as chronic rejection) of a transplanted organ, including acute rejection and vascular remodeling. *Certican* is used in combination with *Neoral* and corticosteroids. First approved in Europe in 2003, *Certican* has completed the EU mutual recognition procedure and is in the process of being launched in the region. In the US, following discussions with the FDA regarding the FDA's requests for additional data, FDA has agreed to hold an Advisory Committee meeting regarding the heart transplantation indication later in 2005. We also plan to begin new Phase III clinical trials in renal and heart transplantation shortly.

- *myfortic* (mycophenolic acid) is a new treatment option that has been studied for use in combination with *Neoral* and corticosteroids to prevent rejection episodes in patients with kidney transplants. *myfortic* has been approved in over 40 countries, including Switzerland (the first approval in 2003), the US, Germany, France, the UK, Australia, India, Brazil and a number of Latin American countries.
- *Simulect* (basiliximab) is a chimeric monoclonal antibody that suppresses interleukin-driven proliferation of T-cells. *Simulect* is used for induction therapy, and is designed to complement *Neoral* or other primary immunosuppressants in preventing acute rejection episodes in kidney transplantation.

# **Compounds in Development**

- FTY720, the first agent in a new class of drugs called Sphingosine 1-Phosphate Receptor (S1P-R) agonists. It is designed to prevent rejection by redirecting lymphocytes away from the transplant graft, preventing lymphocytes from damaging the graft while maintaining the response of lymphocytes against infective agents. FTY720 is being developed for the prevention of renal acute rejection in combination with *Neoral* or FK506 (tacrolimus) and has completed enrollment for phase III clinical trials. In addition, FTY720 is in Phase II development for the treatment of multiple sclerosis. It is licensed from Mitsubishi.
- AEB071 is a T-cell activation blocker in development for the prevention of organ rejection now in Phase I trials.

# **Ophthalmics**

We develop and market products for the treatment of a number of different ophthalmic diseases. Our research and development in this disease area is aimed at the discovery and development of innovative treatments for "Back of the Eye" diseases as well as on "Dry Eye." Both of these areas are characterized by high growth and significant unmet medical needs. The "Back of the Eye" area encompasses several disease areas, such as wet and dry age-related macular degeneration (AMD), diabetic retinopathy, diabetic macular edema and retinitis pigmentosa. The key area of focus within "Back of the Eye" is "wet" AMD, a condition when leaky blood vessels grow across the central portion of the retina, or macula, for unknown reasons and cause bleeding, scar formation and permanent damage, leading to vision loss. Our ophthalmics business has built a leadership position with its flagship product *Visudyne*. In cooperation with collaborator Genentech, we are also developing Lucentis, a VEGF inhibitor that is currently in Phase III clinical trials for the treatment of "wet" AMD and will be marketed by Novartis outside of North America.

# **Key Marketed Products**

- Visudyne (verteporfin) is a light-activated drug used in a two-step procedure that can be performed in a doctor's office. First, the drug is injected intravenously into the patient's arm. A non-thermal laser light is then shone into the patient's eye to activate the drug. First launched in 2000, Visudyne is commercially available in over 75 countries for the treatment of predominantly classic subfoveal choroidal neovascularization (CNV), a major cause of vision loss caused by age-related macular degeneration (AMD). It is also approved in over 40 countries for the treatment of occult subfoveal CNV secondary to AMD (including the EU, where it gained approval in 2002). In addition, Visudyne is approved in over 45 countries, including the EU, US and Canada for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In Japan, Visudyne was recently approved for all types of subfoveal CNV secondary to AMD. Further geographic expansion is planned, including China. Visudyne is licensed from QLT.
- Zaditor/Zaditen (ketotifen) is an eye drop that provides fast and lasting relief of symptoms in patients suffering from ocular allergy. Zaditen works through multiple mechanisms of action to

provide relief within minutes and a duration of action of up to 12 hours. *Zaditen* was first launched in Japan and has been approved in more than 60 countries, including the US, where it is marketed as *Zaditor*, and the EU.

## New Indications in Development

- *Elidel* (pimecrolimus), is currently in Phase II development for the treatment of dry eye in a novel drops formulation and for blepharitis in a novel eye ointment formulation.
- Sandostatin LAR (octreotide acetate) is in Phase III development for diabetic retinopathy. This condition affects approximately 25-30% of patients with diabetes and is one of the leading causes of blindness in people of working age. There are currently no pharmacological treatments available to treat diabetic retinopathy.
- *Visudyne* (verteporfin) is in development for an additional indication. Phase III trials are ongoing in occult CNV secondary to AMD.

# **Compounds in Development**

- Lucentis<sup>™</sup> (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to VEGF. It is designed to penetrate the retina to decrease permeability and inhibit the formation of choroidal neovascularization, which leads to blindness in AMD patients. It is currently in Phase III development for the treatment of "wet" AMD. We have licensed the right to develop and market Lucentis<sup>™</sup> outside of North America from Genentech. Data from two Phase III trials are expected in 2005. Submission for EU approval is planned for 2006.
- PIR335 has been terminated.

#### **Principal Markets**

The Pharmaceuticals Division has a commercial presence in approximately 140 countries worldwide, but net sales are generally concentrated in the US, Europe and Japan, which together accounted for 85% of 2004 net sales. The following table sets forth certain data relating to our principal markets in the Pharmaceuticals Division.

Pharmaceuticals	Net Sales 2004	
	(\$ millions)	(%)
United States	7,368	40
Americas (except the United States)	1,244	7
Europe	6,370	34
Japan	2,081	11
Rest of the World	1,434	8
Total	18,497	100

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

#### Production

The primary goal of our manufacturing and supply chain management program is ensuring the uninterrupted, timely and cost-effective supply of products that meet all product specifications. To achieve this objective, we manufacture our products at five bulk chemical and 15 pharmaceutical production facilities as well as two biotechnology sites. Bulk chemical production involves the manufacture of therapeutically active compounds, mainly by chemical synthesis or by a biological process such as fermentation. Pharmaceutical production involves the manufacture of "galenical" forms of pharmaceutical products such as tablets, capsules, liquids, ampoules, vials and creams. Major bulk chemical sites are located in Basel, Switzerland; Grimsby, UK; and Ringaskiddy, Ireland. Significant pharmaceutical production facilities are located in Stein, Switzerland; Wehr, Germany; Torre, Italy; Barbera, Spain; Suffern, New York; Sasayama, Japan, and in various other locations in Europe, including France, the UK and Turkey. Our two biotechnology plants are in Switzerland and France.

During clinical trials, which can last several years, the manufacturing process for a particular product is rationalized and refined. By the time clinical trials are completed and products are launched, the manufacturing processes have been extensively tested and are considered stable. However, improvements to these manufacturing processes may continue throughout a product's life cycle.

While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances. The manufacture of our products is heavily regulated, making supply never an absolute certainty. If we or our third party suppliers fail to comply fully with such regulations then there could be a recall or a government-enforced shutdown of production facilities, which in turn could lead to product shortages. We have implemented a global manufacturing strategy to maximize business continuity.

Raw materials for the manufacturing process are either produced in-house or purchased from a number of third party suppliers. Where possible, our policy is to maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers. However, our ability to do so may at times be limited by regulatory requirements. We monitor market developments that could have an adverse effect on the supply of essential materials. All raw materials we purchase must comply with our quality standards. Overall, prices are not volatile for materially significant raw materials.

# Marketing and Sales

The Pharmaceuticals Division serves customers with approximately 6,000 field force representatives in the US, and an additional 13,000 in the rest of the world. These trained representatives, where permitted by law, present the economic and therapeutic benefits of our products to physicians, pharmacists, hospitals, insurance groups and managed care organizations.

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

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

#### Competition

The global pharmaceutical market is highly competitive and we compete against other companies selling branded prescription pharmaceutical products. These companies include Abbott, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Sanofi-Aventis, Schering-Plough and Wyeth. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

As is the case with other pharmaceutical companies selling patented pharmaceuticals, Novartis faces an increasing challenge from companies selling generic forms of our products following the expiry of patent protection. Generic companies may also gain entry to the market through successfully challenging our patents, but we vigorously defend our intellectual property rights from generic challenges that infringe upon our patents and trademarks. We also face competition from over-the-counter (OTC) products that do not require a prescription from a physician.

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

#### **Research and Development**

We are among the leaders in the pharmaceuticals industry in terms of research and development investment. In 2004, we invested approximately \$3.5 billion in Pharmaceuticals Division research and development, which represents 18.8% of the Division's total net sales. Our Pharmaceuticals Division invested \$3.1 billion and \$2.4 billion on research and development in 2003 and 2002 respectively. There are currently more than 75 projects in clinical development. In 2005, as a result of these efforts, we expect to launch *Aclasata* and *Focalin XR*, as well as new indications or formulations for *Gleevec/Glivec*, *Diovan*, *Femara*, *Zelnorm/Zelmac* and *Xolair*, in various markets worldwide.

We have long term research commitments totaling \$1.2 billion as of December 31, 2004, including \$0.6 billion in milestone payments. We intend to fund these expenditures from internally developed resources.

The discovery and development of a new drug is a lengthy process, usually requiring 10 to 12 years from the initial research to bringing a drug to market, including six to eight years from Phase I clinical trials to market. At each of these steps, there is a substantial risk that we will not achieve our goals. In such an event, we may be required to abandon a product in which we have made a substantial investment.

# Research program

The discovery of new drugs is the responsibility of our Research program. This is a complex and challenging process which is split into different phases. These phases provide tools that allow our Research team to manage and benchmark their activities. Milestones are established for each phase of the evaluation process. Candidates only advance to the next stage if defined sets of criteria are met. The primary goal of our Research program is to determine that a compound is ready for Proof of Concept in humans. To determine whether a compound may be tested in humans, we must invest significant resources in preclinical activities to satisfy safety requirements, including toxicology studies. Only those compounds that pass this more comprehensive series of preclinical testing (on average, about one in ten candidates) advance to the development stage of a drug's life-cycle. See "—Clinical development program."

In 2003, we established the Novartis Institutes for BioMedical Research (NIBR), headquartered in Cambridge, Massachusetts, with affiliates worldwide. NIBR is redefining drug discovery in the era which began with the completion of the human genome sequence. Our strategies at NIBR include integrating previously segregated disciplines, fostering interaction among scientists, both within and outside of Novartis and investing and advancing new discovery approaches. Our goal is to produce more relevant, predictable drug discovery and offer new and better medicines for patients worldwide.

Completed in 2004, our Cambridge facility contains a total of 75,300 square meters of laboratory and office space. It is expected to house over 800 scientists and technology experts, and approximately 1,000 employees in total.

Several of our discovery research platforms, including Functional Genomics, Molecular and Developmental Pathways, Models of Disease, Global Discovery Chemistry, and Epigenetics, are based at our Cambridge headquarters. Disease-area research groups in Cambridge include cardiovascular disease, diabetes and metabolism, infectious disease and oncology.

Outside of the Cambridge site, an additional 2,000 scientists and technology experts conduct research in Switzerland, Austria, the UK, Japan and various other US sites. Research is conducted in the areas of Neuroscience, Autoimmune Disease (including Dermatology, Transplantation, and Arthritis) and Respiratory Disease at these sites. In addition, research platforms such as Discovery Technologies and Information Knowledge and Management are headquartered in the NIBR site in Basel.

#### Development program

The testing of new drugs in humans, to determine whether they are safe and effective, is the focus of our Development program. Clinical trials of drug candidates generally proceed through three phases. In Phase I clinical trials, a drug is usually tested with about 20 to 80 normal, healthy volunteers. The tests study the drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action. In Phase II clinical trials, the drug is tested in controlled studies of approximately 100 to 300 volunteer patients (*i.e.*, persons with the targeted disease) to assess the drug's effectiveness and safety, and to establish a proper dose. In Phase III clinical trials, the drug is further tested on larger numbers of volunteer patients (in some cases more than 15,000 patients in total) in clinics and hospitals. In each of these phases, physicians monitor volunteer patients closely to determine the drug's efficacy and to identify possible adverse reactions. The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug. See "—Regulation."

# Initiatives to optimize the research and development processes

We are working to be more efficient in selecting candidate drugs for development. For example, we are now better able to select the best compounds for development by having senior management focus on development projects at an early stage. Where possible we run early proof of concept studies in patients which include biomarkers for potential efficacy and which enable us to make an earlier evaluation of the probability that the compound could be successfully developed into a marketable product. Under another initiative, special teams work to develop late stage products more quickly. The goal is to improve the likelihood of therapeutic and commercial success, which should reduce development costs and decrease time to market. In several other initiatives we are improving electronic management of the clinical trial processes, including data capture and transfer, as well as electronic storage and archiving of study data and documents. Most recently we have initiated electronic submissions to health authorities, vastly reducing the quantity of paper documents which need to be submitted and also enabling faster and more efficient review of data by health authorities. Overall, these initiatives have reduced clinical trial outsourcing, have improved data quality and speed of clinical trial reporting, substantially reduced the time between initial research and the introduction of the drug to market, and have provided us with considerable cost savings.

# Alliances and acquisitions

Our Pharmaceuticals Division forms alliances with other pharmaceutical and biotechnology companies, and with academic institutions in order to develop new products, acquire platform technologies and access new markets. We license products that complement our current product line and are appropriate to our business strategy. Therapeutic area strategies have been established to focus on alliances and acquisition activities for key disease areas/indications that are expected to be growth drivers in the future. We review products and compounds we are considering licensing using the same criteria as we use for our own internally discovered drugs.

#### Regulation

The international pharmaceutical industry is highly regulated. Regulatory authorities around the world administer numerous laws and regulations regarding the testing, approval, manufacturing,

importing, labeling and marketing of drugs, and also review the safety and efficacy of pharmaceutical products. Further controls exist on the non-clinical and clinical development of pharmaceutical products. These regulatory requirements are a major factor in determining whether a substance can be developed into a marketable product, and the amount of time and expense associated with that development.

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

To register a pharmaceutical product, a registration dossier containing evidence establishing the quality, safety and efficacy of the product must be submitted to regulatory authorities. Generally, a therapeutic product must be registered in each country in which it will be sold. In every country, the submission of an application to a regulatory authority does not guarantee that approval to market the product will be granted. Although the criteria for the registration of therapeutic drugs are similar in most countries, the formal structure of the necessary registration documents varies significantly from country to country. It is possible that a drug can be registered and marketed in one country while the registration authority in a neighboring country may, prior to registration, request additional information from the pharmaceutical company or even reject the product. It is also possible that a drug may be approved for different indications in different countries.

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

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

## United States

In the US, applications for drug registration are submitted to and reviewed by the FDA. The FDA regulates the testing, approval, manufacturing, importing, labeling and marketing of pharmaceutical products intended for commercialization in the US. The FDA also monitors all pharmaceutical products currently on the US market. The pharmaceutical development and registration process is typically intensive, lengthy and rigorous. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's quality, safety and efficacy, then the company may file a New Drug Application ("NDA") for the drug. The NDA must contain all the scientific information that has been gathered about the drug and typically includes information regarding the clinical experiences of all patients tested in the drug's clinical trials. A supplemental new drug application ("sNDA") must be filed for a line extension of, or new indications for, a previously registered drug.

Once an NDA is submitted, the FDA assigns reviewers from the fields of biopharmaceuticals, chemistry, medicine, microbiology, pharmacology/toxicology, statistics and labeling. After a complete review, these experts then provide written evaluations of the NDA, including a recommendation. These recommendations are consolidated and are used by the FDA in its evaluation of the NDA. Based on that evaluation, FDA then provides to the NDA's sponsor an approval, or an approvable, or non-approvable letter. The approvable and non-approvable letters will state the specific deficiencies in the NDA which

need to be addressed. The sponsor must then submit complete responses to the deficiencies in order to restart the review procedure.

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

## **European Union**

In the EU, there are two main procedures for application for authorization to market pharmaceutical products in all of the EU Member States, the Centralized Procedure and the Mutual Recognition Procedure. It is also possible to obtain a national authorization for products intended for commercialization in a single EU member-state only, or for line extensions to existing national product licenses.

Under the Centralized Procedure, applications are made to the European Medicines Agency (EMEA) for an authorization which is valid across all EU member states. The Centralized Procedure is mandatory for all biotechnology products and optional for other new chemical compounds or innovative medicinal products. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's quality, safety and efficacy, then the company may submit an application to the EMEA. The EMEA then receives and validates the application, and appoints a Rapporteur and Co-Rapporteur to review it. The entire review cycle must be completed within 210 days, although there is a "clock stop" at day 120, to allow the company to respond to questions set forth in the Rapporteur/Co-Rapporteur's Assessment Report. When the company's complete response is received by the EMEA, the clock restarts on day 121. If there are further aspects of the dossier requiring clarification, the EMEA will then request an Oral Explanation on day 180, in which the sponsor must appear before the EMEA's Scientific Committee (the CPMP) to provide the requested additional information. On day 210, the CPMP will then take a vote to recommend the approval or non-approval of the application. The final decision under this Centralized Procedure is an EU Community decision which is applicable to all Member States. This decision occurs on average 90 days after a positive CPMP recommendation.

Under the Mutual Recognition Procedure (MRP), the company first obtains a marketing authorization by a single EU member-state. Subsequently, the company may seek mutual recognition of this first authorization from some or all of the remaining EU Member-States. Then, within 90 days of this initial decision, each Member State reviews the application and can issue objections or requests for additional information. On Day 90, each Member State must be assured that the product is safe and effective, and that it will cause no risks to the public health. Once agreement has been reached, each Member State grants separate marketing authorizations for the product.

After the Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMEA (Centralized Procedure) or to the National Health Authorities (MRP). These Marketing Authorizations must be renewed on a 5 year basis.

#### Japan

In Japan, applications for new products are made through the Pharmaceutical and Medical Devices Agency (PMDA). After a data reliability survey and a Good Clinical Practice inspection are carried out by the PMDA, a team evaluation is carried out by the Pharmaceutical and Medical Devices Evaluation Center (PMDEC) of the PMDA. Its results are passed to PMDA's external experts who then report back to the PMDA. After a further team evaluation, a report is provided to the Ministry of Health, Labor and Welfare (MHLW), which makes a final determination for approval and refers this to the Central Pharmaceuticals Affairs Council (CPAC) which then advises the MHLW on final approvability. Drug

manufacturing or import license approval is issued by the local prefecture government. Once the MHLW has approved the application and has listed its national health insurance price, the company can make the new drug available for physicians to prescribe and obtain reimbursement. For some medications, the MHLW requires additional post-approval studies (Phase IV) to evaluate safety, effects and/or to gather information on the use of the product under special conditions. The MHLW also requires the Sponsor to submit safety reports.

## **Price Controls**

In many of the markets where we operate, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. Due to increasing political pressure and governmental budget constraints, we expect these mechanisms to remain in place—and to perhaps even be strengthened—and to have a negative influence on the prices we are able to charge for our products.

In the US, debate over the reform of the healthcare system has resulted in an increased focus on pricing. Although there are currently no government price controls over private sector purchases in the US, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under some government healthcare programs. In the absence of government pricing regulations, managed care has become a potent force in the US market place that increases downward pressure on the prices of pharmaceutical products. In addition, the recently enacted Medicare reform legislation could ultimately enable the US government to use its enormous purchasing power to demand additional discounts from pharmaceutical companies. At the same time, this legislation could increase the volume of pharmaceutical drug purchases, perhaps offsetting, at least in part, potential additional price discounts. It is too soon to predict the full impact of this new legislation with certainty. Another potential influence on pricing in the US is the ongoing efforts by consumers and others to obtain our products from distributors in Canada, which has relatively stringent price controls. Such imports from Canada to the US are currently illegal. However, there are ongoing political efforts to change the legal status of such imports.

In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general in the EU, particularly with regard to prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert commercial pressure on pricing within a country. The EU enlargement (with 10 countries having joined the EU in 2004) will probably complicate the environment and have some influence on prices in the region and parallel trade.

In Japan, the MHLW reviews the prices of individual pharmaceutical products every two years. In the past, these reviews have resulted in price reductions. The Japanese government is currently undertaking a healthcare reform initiative, and the pharmaceutical pricing system is one of the issues being reviewed. In particular, the government is reviewing the pricing of older products, including the biannual reduction of reimbursement prices adjusted for actual discounts given.

#### **Intellectual Property**

We attach great importance to patents, trademarks, and know-how in order to protect our investment in research and development, manufacturing and marketing. It is our policy to seek the broadest possible protection for significant product developments in all major markets. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen. The protection offered by such patents extends for varying periods depending on the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage. We monitor our competitors and vigorously challenge infringements of our intellectual property.

In general, published pharmaceutical industry benchmarks show that we are at a comparatively low risk of loss of significant amounts of revenue due to patent expirations. As examples, we have basic patent protection (including extensions) on valsartan (the active ingredient used in our best-selling product *Diovan*) until 2012 in the US, until 2011 in the major countries of the EU, and until 2013 in Japan. We have basic patent protection (including extensions) on imatinib (the active ingredient used in our leading product *Gleevec/Glivec*) until January 2015 in the US (excluding pediatric extension), until 2016 in the major EU countries, and until 2013 in Japan.

However, patent protection is no longer available in several major markets for the active substances used in a number of our Pharmaceuticals Division's leading products:

- *Neoral.* Patent protection exists for the *Neoral* micro-emulsion formulation and other cyclosporin formulations through 2009 and beyond in major markets. Despite this protection, generic cyclosporin products competing with *Neoral* have entered the transplantation market segment in the US, Germany, Japan, Canada and elsewhere. We have filed patent infringement actions against manufacturers of these generic products. However, except in one lawsuit in Canada, we have so far not succeeded in obtaining an injunction against any of the manufacturers that we have sued.
- Sandostatin. Basic patent protection for the active ingredient of Sandostatin SC has expired in the US, Japan, Germany and the UK, and it will expire in 2006 in France and 2007 in Italy. Several parties have filed applications to market generic versions of Sandostatin SC in the US. We have not, so far, sued any for patent infringement. However, patent protection extending to 2010 (and 2013 and beyond in the US) continues in major markets for Sandostatin LAR, a long-acting version of Sandostatin which represents a significant and growing proportion of our sales in this product family.
- Lotrel/Cibacen/Lotensin/Cibadrex. The basic benazepril substance patent protection for Cibacen/ Lotensin/Cibadrex has expired in the US and Japan, and will expire in 2005-08 in major markets in the EU. However, Lotrel, which is a combination of benazepril and amlodipine besylate, is patented in the US until 2017. Teva and Dr. Reddy's Laboratories have challenged this patent. Dr. Reddy's is seeking marketing approval for a different benazepril combination, using amlodipine maleate rather than amlodipine besylate. Because of this difference, the Dr. Reddy's product, if brought to market, would not be automatically substitutable in the US for Lotrel. However, Teva is seeking marketing approval for the same benazepril combination as Lotrel, and is thus seeking to bring a fully substitutable product to the US market. We have sued Teva and Dr. Reddy's in the US for patent infringement. The Dr. Reddy's case is currently stayed.
- Lamisil. The active ingredient in Lamisil is covered generically, but not mentioned specifically, in a patent family which has expired. Another patent family specifically discloses and covers the active ingredient and expires in the US in 2006, and in 2005-07 in Japan and major EU countries. The specific US patent had been challenged by Dr. Reddy's Laboratories in the US. Dr. Reddy's has since withdrawn its suit and conceded that this patent is valid and enforceable.
- *Miacalcin/Miacalcic*. The specific Novartis formulation of this product is covered by patents which will expire in the US in 2015. However, patents on the Novartis formulation have expired in a number of major countries and will expire in Italy in 2006. Apotex has applied to the FDA for the right to sell a generic version of *Miacalcin* using the Novartis formulation. We have sued Apotex for infringement. Two other companies have applied to the FDA for the right to sell a generic version of *Miacalcin* using the Novartis formulation. We have sued Apotex for infringement. Two other companies have applied to the FDA for the right to sell a generic version of *Miacalcin* based on a different formulation. We have not sued these companies.

- *Exelon*. The active ingredient in *Exelon* is covered by a compound patent (granted to Proterra, AG and licensed to us), which presently expires in 2007, and has been determined by the FDA to qualify for patent term extension until 2012. In addition, we hold an isomer patent on *Exelon* which expires in 2014. Dr. Reddy's, Sun Pharmaceuticals and Watson Pharmaceuticals have filed applications to market a generic version of *Exelon* in the US. Together with Proterra, we have sued all three parties for patent infringement.
- Focalin. The active ingredient in Focalin is covered by patents (granted to Celgene Corporation and licensed to us) through 2015 in the US and 2018 in other markets. Teva has challenged these patents and has filed an application for a generic version of Focalin in the US. Together with Celgene, we have sued Teva for patent infringement.
- *Trileptal*. Patent protection for *Trileptal's* active ingredient has expired in major countries. In the US, New Chemical Entity data exclusivity under the Hatch-Waxman Act of 1984 is currently scheduled to expire in January 2005. However, we have applied for a six-month extension of this exclusivity period under the Hatch-Waxman pediatric exclusivity provisions. At the same time, we have pending patent filings relating to our marketed formulations of *Trileptal*, which, if granted, would expire in 2018 in major countries, including the US.
- *Starlix.* The active ingredient in *Starlix* is covered by Ajinomoto patents. The basic US patent will expire in 2006, but a request to extend the term of the patent until 2009 has been filed. In late January 2005 a third party informed us that they have filed an ANDA application to market a generic version of *Starlix* in the US. We are assessing that information and will respond appropriately.
- *Foradil*. Patent protection for *Foradil's* active ingredient has expired in major countries. In the US, Hatch-Waxman data exclusivity is currently scheduled to expire in February 2006.
- *Voltaren*. *Voltaren* is off-patent. As a result, revenue from *Voltaren* has declined, and may decline significantly further over the next few years.

The loss of patent protection can have a significant impact on our Pharmaceuticals Division. We work to offset these negative effects by developing and patenting inventions that result in process and product enhancements and by positioning many of our products in specific market niches. However, there can be no assurance that this strategy will be effective in the future to extend competitive advantage, or that we will be able to avoid substantial adverse effects from future patent expirations.

# **CONSUMER HEALTH**

Our Consumer Health Division is a world leader in the research, development, manufacturing and marketing of a wide range of competitively differentiated products that restore, maintain or improve the health and well being of our consumers. The business of our Consumer Health Division is conducted by a number of affiliated companies throughout the world. Created in July 2002, the Consumer Health Division consists of the following Business Units: OTC self-medication, Animal Health, Medical Nutrition (including the Nutrition & Santé franchise), Infant & Baby, and CIBA Vision. Sandoz (generics) was a Business Unit of the Consumer Health Division until December 31, 2004, after which time it became a separate Division. Therefore, for reporting purposes, the 2004 results of the Sandoz business are included with the results of the Consumer Health Division.

As of December 31, 2004, the affiliates of the Consumer Health Division employed 32,548 associates worldwide. In 2004, the affiliates of the Consumer Health Division (including Sandoz) achieved consolidated net sales of \$9.75 billion, which represented 35% of the Group's total net sales, and invested \$0.6 billion in research and development.

Our Consumer Health Division places considerable emphasis on the development of strong, consumer-oriented and trustworthy brands. We believe each Business Unit has a leading market position in growth-oriented healthcare segments beyond our core pharmaceuticals business, and provides essential,

high quality health-related products. In order to deliver accelerated sales growth, and to achieve leadership positions in the fields in which we compete, our Consumer Health Division seeks to give voice to the consumer and to determine the consumer's needs and desires.

In the dynamic world of consumer healthcare, aging populations are increasingly affluent and becoming more knowledgeable about their health and the benefits of self-medication. The success of each Business Unit depends upon its ability to anticipate and meet the needs of such consumers and of health professionals worldwide.

#### **SANDOZ**

In 2004, Sandoz was still a Business Unit of our Consumer Health Division. As of January 1, 2005, it became a separate Division organized as a Retail Generics company which also operates two other businesses, Industrial Products and Biopharmaceuticals. The business of Sandoz is conducted by a number of affiliated companies and sells to approximately 140 countries. Sandoz is a world leader in the development, manufacturing and marketing of pharmaceutical products and substances which are no longer protected by patents. As of December 31, 2004, Sandoz employed 13,397 associates worldwide. In 2004, the affiliates of Sandoz achieved consolidated net sales of \$3.0 billion, which represented 11% of the Group's total net sales.

Because Sandoz was part of the Consumer Health Division until December 31, 2004, for reporting purposes, the 2004 results of the Sandoz business are included with the results of the Consumer Health Division.

In August 2004, we acquired Sabex Holdings Ltd., a Canadian generic company with a leading position in injectable products. This acquisition provides Sandoz with strong growth opportunities in injectable generics. This acquisition also gives Sandoz a new operational presence in Canada, the world's sixth largest generics market, and offers the opportunity to increase sales in Canada of our existing portfolio of solid-dosage-form products.

In June 2004, we acquired the Danish generics company Durascan A/S from AstraZeneca plc. This acquisition provides Sandoz with a leadership position in the Danish market. In addition, Durascan's broad portfolio of generic products offers growth opportunities for Sandoz throughout the Nordic region.

In 2003, we united 14 of our generics company brands under the single global umbrella name Sandoz, to strengthen recognition and leverage share of voice in the highly competitive marketplace for generic products. This initiative capitalizes on the strong reputation of the Sandoz name, which has a high level of awareness and trust among physicians, pharmacists and patients.

In 2002, we acquired Lek Pharmaceuticals d.d., Slovenia's largest pharmaceuticals company. This acquisition provided Sandoz with a leadership position in the sales of generic pharmaceutical products in Central and Eastern Europe and in the former Soviet Union. For the time being, Lek products will continue to be sold under that well-regarded name, as agreed between the management of Novartis and Lek.

In 2004, Sandoz competed in three business franchises: finished dosage forms (the Generics Pharmaceuticals Business), active pharmaceutical ingredients and intermediates (the Industrial Products Business) and Biopharmaceuticals (the Biopharmaceuticals Business).

In the Generics Pharmaceuticals Business (now Retail Generics), we develop and manufacture drugs that are no longer protected by patents into finished dosage forms, and we sell them to wholesalers, pharmacies, hospitals and other healthcare outlets around the world. In the Industrial Products Business, we develop and manufacture off-patent active pharmaceutical ingredients and intermediates and sell them worldwide to customers who use them to manufacture finished goods. In developing our new Biopharmaceuticals Business, we are seeking to leverage our technology and expertise to develop, manufacture and market high-quality biopharmaceutical products, such as protein hormones and other human proteins, to be sold as substitutes for branded biopharmaceutical products after their patents have expired. Sandoz is also an important manufacturer of biopharmaceuticals for a number of third parties.

In 2004, Sandoz net sales decreased by approximately 1% in local currencies. The business year was characterized by a highly competitive environment, especially in the US and Germany, and the acquisitions of Durasacan A/S and Sabex Holdings Ltd.

Approximately 76% of our Sandoz net sales are derived from our Generics Pharmaceuticals Business, approximately 21% of net sales are derived from our Industrial Products Business and approximately 3% are attributable to the Biopharmaceuticals Business.

In 2004, net sales of our Generics Pharmaceutical Business in the US decreased by 11%, mainly driven by fierce competition, the erosion of prices and volume losses. In particular, sales of our amoxicillin/potassium clavulanate product (a generic version of the antibiotic Augmentin<sup>®</sup>), a key driver of sales in 2003, were hurt by increasing competition.

In Germany, the second largest market for our Generics Pharmaceutical Business products, net sales were hurt by significant price competition. In addition, the introduction of new regulations in 2004 caused a significant decline of the number of products that were reimbursable.

In other key European markets, our Generics Pharmaceutical Business achieved double-digit net sales growth. These markets included France and Russia.

In 2004, our Industrial Products Business enlarged its activities in the field of modern sterile penicillins (Amoxicillin Sodium, sterile combinations with Clavulanic Acid), in generic macrolides (Clarithromycin, Azithromicin), and advanced cephalosporin intermediates. The Industrial Products Business was negatively affected by low prices offered by Asian suppliers and a strong Euro, the main currency in the production network. As a consequence, Sandoz announced the closure of one production line in Italy.

In 2004, our Biopharmaceuticals Business continued the development of follow-on biologics, leveraging more than 20 years of biotech experience. With its biopharmaceuticals portfolio, Sandoz is at the forefront of emerging regulatory policies for follow-on biologics in Europe and the US. Sandoz is determined to contribute to the availability of safe and effective follow-on biologics. In September 2004, we received the first marketing authorization for the recombinant human growth hormone *Omnitrope* in Australia.

However, in September 2004, Sandoz also received notice from the FDA that the agency was unable to reach a decision on whether to approve an application for the marketing of *Omnitrope*. According to the FDA letter issued to Sandoz, the agency did not identify any deficiencies in the application. However, the FDA stated that it had been unable to reach a final decision on the application due to uncertainty regarding scientific and legal issues.

In addition, in November 2003, the European Commission notified Sandoz about its intent not to proceed with the decision for a marketing authorization for *Omnitrope* under the regulatory pathway chosen by Sandoz. In January 2004, Sandoz filed its complaint to the European Court of First Instance.

# **Recently Launched Products**

The following is a summary of the most important products launched by Sandoz in 2004:

- Levothyroxine (a generic version of Synthroid<sup>®</sup> and Levoxyl<sup>®</sup>, a treatment for hyperthyroidism) was launched in the US in June 2004.
- Ribavarin (a generic version of Rebetol<sup>®</sup>, a treatment for chronic hepatitis C in combination with interferon) was launched in the US in April 2004.

- Paroxetine (a generic version of Paxil<sup>®</sup>, a treatment for major depressive disorder, obsessive compulsive disorder, panic disorder and social anxiety disorder) was launched in the UK in May, in the US in June, in France in August, and in the Netherlands in September 2004.
- Ramipril (a generic version of Altace<sup>®</sup>, a treatment for hypertension) was launched in the Netherlands in January 2004 followed by launches in other European countries in 2004.
- Cefuroxime Axetil (a generic version of Zinnat<sup>®</sup>, an antibiotic) was launched in Germany in January 2004.
- Pravastatin (a generic version of Pravachol<sup>®</sup>, a cholesterol lowering drug) was launched in Spain in April and in the UK, Germany, the Netherlands and Denmark in August 2004.
- Amlodipine mesylate (a generic version of Norvasc<sup>®</sup>, a treatment for hypertension) was launched in the Nordic region (Denmark, Finland, Norway) and in the Netherlands in March, and in Austria in July 2004.
- Clarithromycin (a generic version of Biaxin<sup>®</sup>, an antibiotic) was launched in Germany in November, Croatia in May, and in Finland and Denmark in July 2004.
- Setraline (a generic version of Zoloft<sup>®</sup>, a treatment for depression) was launched in Spain in August 2004.

#### **Key Marketed Products**

The following table describes the key marketed products for Sandoz. Not all products are available in all markets.

# **Generics Pharmaceuticals Business**

Product	Originator Drug	Description
Amoxicillin/clavulanic acid	Augmentin®	anti-infective
Omeprazole	Prilosec®	ulcer and heartburn treatment
Citalopram	Celexa®	anti-depressant
Loratadine	Claritin®	antihistamine
Atenolol	Tenoric®	anti-hypertension
Penicillin		anti-infective
Lisinopril	Prinivil®	ACE inhibitor
Ranitidine	Zantac <sup>®</sup>	anti-ulcerant
Metformin	Glucophage®	anti-diabetic
Terazosin	Hytrin®	anti-hypertension and
		benign prostatic hyperplasia
Enalapril	Lexxel®	ACE inhibitor
Metoprolol	Lopressor®	Anti-hypertension

#### **Industrial Products Business**

Active Ingredient	Description
Oral and sterile penicillins	Anti-infectives
Oral and sterile cefalosporins	Anti-infectives
Clavulanic acid and mixtures with clavulanic acid	β-lactam inhibitors
Classical and semisynthetic erythromycins	Anti-infectives
Tiamuline	Anti-infectives
Lovastatin, Simvastatin, Pravastatin	Statins
Vancomycin	Anti-infectives
Lisinopril	ACE-inhibitor
Thyroxine	Hormones
Intermediates	Description
Various cephalosporin intermediates	Anti-infectives
Erythromycin base	Anti-infectives
Various crude compounds produced by fermentation	Cyclosporine, ascomysine, rapamycine, mycophenolic acid, etc.

#### **Principal Markets**

The principal markets for Sandoz are the two largest generics markets in the world: the US and Europe. The following table sets forth the aggregate 2004 net sales of Sandoz by region:

Sandoz	Net Sales 2004	
	(\$ millions)	(%)
United States	981	32
Americas (except the United States)	187	6
Europe	1,448	48
Rest of the World	429	14
Total	3,045	100

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

## Production

We manufacture our Sandoz products at 28 production facilities around the world. Among these, our principal production facilities are located in Kundl, Austria; Mengeš and Ljubljana, Slovenia; Broomfield, US; Stryków, Poland; Kalwe, India; Palafolls, Spain; and Boucherville, Canada. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances. The manufacture of our products is heavily regulated, making supply never an absolute certainty. If we or our third party suppliers fail to comply fully with such regulations then there could be a recall or a government-enforced shutdown of production facilities, which in turn could lead to product shortages.

Active pharmaceuticals ingredients are manufactured in our facilities or purchased from a number of our affiliates and third-party suppliers. Where possible, our policy is to maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers and competitive material sourcing can be assured. However, our ability to do so may at times be limited by regulatory requirements. We monitor market developments that could have an adverse effect on the supply of essential active pharmaceutical ingredients. All active pharmaceutical ingredients that we purchase must comply with our quality standards. In order to sustain cost competitiveness and reliable quality, we produce some of our active pharmaceutical ingredients, like penicillins, by vertical integration, using modern bio-technological methods. These methods include fermentation processes, chemical syntheses and physical production methods, such as sterile processing. We are constantly working to develop other new manufacturing processes.

We obtain agricultural raw materials such as flours and sugars from multiple suppliers based in the EU. We obtain chemicals and other raw materials from suppliers around the world. The raw materials we purchase are generally subject to market price fluctuations. We seek to avoid these fluctuations, where possible, through the use of long-term supply contracts.

## **Marketing and Sales**

In our Generics Pharmaceuticals Business, we have a broad portfolio of off-patent drugs that we sell to wholesalers, pharmacies, hospitals, and other healthcare outlets. Depending on the structure of the local market, customers are serviced either by the field service team of the local Sandoz affiliate or by established partners or joint venture associates.

Our Industrial Products Business supplies our Generics Pharmaceutical Business and the pharmaceutical industry worldwide with a broad portfolio of active pharmaceutical ingredients and intermediates.

In response to rising healthcare costs, many governments and private medical care providers, such as health maintenance organizations (HMOs), have instituted reimbursement schemes that favor the substitution of branded pharmaceuticals by generics. In the US, generic substitution statutes have been enacted by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug for the brand-name version of the drug. In Europe, the use of generic drugs is growing. But in some EU countries, reimbursement practices do not create an efficient incentive for generic substitution. As a result, generic penetration rates in many European countries are still below those reached in the US.

## Competition

Other major companies selling finished dosage form generic pharmaceutical products are Alpharma, Barr, Dr. Reddy's, Hexal, Ivax, Krka, Merck Generics, Mylan, Pliva, Ranbaxy, Ratiopharm, Stada, Teva and Watson.

Other companies selling active pharmaceutical ingredients & intermediates are Antibioticos, Dr. Reddy's, DSM-Anti-Infectives, Ranbaxy and Teva, as well as certain East Asian manufacturers.

The market for generic products is characterized by increasing demand for high-quality pharmaceuticals which can be produced at lower costs due to minimized initial research and development investments. Increasing pressure on healthcare expenditures and numerous patent expirations have created a favorable market environment for the generics industry. This positive market trend, however, brings increased competition within the generics industry, leading to ongoing price pressure on generic pharmaceuticals.

In addition, branded pharmaceutical companies have responded to the increased competition from generic products by licensing their branded products to generic companies (the so-called "authorized generic"). By doing so, branded companies participate in the conversion of their branded product to generics. Consequently, generic companies that were not in a position to compete on a specific product are allowed to enter the generic market using the innovator's product. The innovator's authorized generic is not, at this time subject to the Hatch-Waxman rules regarding exclusivity. See "—Regulation." As a

result, the company that launches an authorized generic typically enters the market at the same time as the generic exclusivity holder. This tends to reduce the value of the exclusivity for the first generic.

# **Research and Development**

Before a generic drug may be marketed, intensive technical and clinical development work must be performed in order to demonstrate the bioequivalency of the generic drug to the original branded drug. Nevertheless, research and development costs associated with generic drugs are much lower than those of their original counterparts. As a result, off-patent drugs can be offered for sale at prices much lower than those of patented drugs, which must recoup substantial basic research and development costs through higher prices over the life of the product's patent.

Currently, the affiliates of Sandoz employ about 1000 Research and Development staff who explore alternative routes for the manufacture of known compounds and who aim to develop innovative forms of generic drugs. These associates are based worldwide, including facilities in Kundl and Schaftenau, Austria; Mengeš and Ljubljana, Slovenia; Kolshet, India; Boucherville, Canada; and Dayton, New Jersey.

In 2004, Sandoz invested \$286 million in research and development, which amounted to 9.4% of net sales. We have long-term research commitments totaling \$61 million in the aggregate as of December 31, 2004. We intend to fund these expenditures from internally generated resources.

#### Regulation

The Hatch-Waxman Act in the US (and similar legislation in the EU and in other countries) eliminated the requirement that generic drug manufacturers repeat the extensive clinical trials which are required for originator drugs, so long as the generic version could be shown to be of identical quality and purity, and to be biologically equivalent to the original branded drug.

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

In the EU, decisions on bioequivalence can be made by the EMEA under the Centralized Procedure, or by a single member state, after which the MRP may be followed. See "Pharmaceuticals—Regulation— European Union." Companies may submit Abridged Applications for approval of a generic pharmaceutical product, based upon its "essential similarity" to a medicinal product authorized and marketed in the EU for not less than ten years.

#### **Intellectual Property**

Wherever possible our products are protected by our own patents. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may

also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

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

In addition, we face the risk that generic competitors may file patents to protect product developments which could block Sandoz's own development projects. If this were to occur we could be forced to terminate a development program, which would require us to write-off any resources invested in that project, and would mean a loss of revenue.

We are currently involved in litigation in a number of countries with affiliates of AstraZeneca regarding omeprazole, our generic version of AstraZeneca's Prilosec®. We launched omeprazole in the US in August 2003. While some of the European cases have been decided in our favor, many of the cases, including the cases pending in the US, may continue for some time. We believe that we will be successful in these lawsuits. However, should AstraZeneca succeed in any or all of the lawsuits, then AstraZeneca will likely seek to recover from us its lost profits for sales it would have made had our product not been on the market.

#### **OTC**

Our Over-the-Counter (OTC) self medication Business Unit is a world leader in the research, development, manufacturing and marketing of products for the treatment and prevention of common medical conditions and ailments, to enhance people's overall health and well being. The business of our OTC Business Unit is conducted by a number of affiliated companies in more than 50 countries. As of December 31, 2004, the affiliates of our OTC Business Unit employed 4,047 associates worldwide. In 2004, the affiliates of our OTC Business Unit achieved consolidated net sales of \$2.0 billion, which represented 7% of the Group's total net sales.

#### **Key Marketed Products**

The OTC Business Unit's main product categories are cough, cold and allergy treatments, gastrointestinal treatments, dermatological treatments, analgesics, vitamins, minerals and supplements, venous disorder treatments and smoking cessation treatment. The major OTC brands are:

# Key brands

Market/segment

Nicotinell/Habitrol	Smoking cessation
Voltaren Emulgel	Topical muscle pain
Sandoz	Minerals
Lamisil <sup>AT</sup> Cream	Athlete's foot treatment
NeoCitran/TheraFlu	Cold and flu treatment
Benefiber/NovaFibra	Fiber supplements
Triaminic	Pediatric cough & colds
Maalox	Antacid
<i>Ex-Lax</i>	Laxative
<i>Gas-X</i>	Anti gas
<i>Otrivin</i>	Nasal decongestant
Fenistil	Wound healing

In 2004, the OTC Business Unit had a number of key brand achievements:

- *Voltaren*, OTC's analgesic franchise continued its exceptional growth in all regions driven by new launches of patch and systemic forms as well as a range of line extensions. In Germany, *Voltaren* became the number two OTC brand behind Bayer's Aspirin and worldwide the brand surpassed the \$200 million threshold for the first time.
- *Theraflu* and *Triaminic* were strengthened with the innovative launch of *Thin Strips*, a novel delivery form for the company's cough and cold medicines. Our OTC Business Unit was the first company to launch products containing an active pharmaceutical substance using this technology.
- *Nicotinell/Habitrol*, our smoking cessation franchise, had another year of solid growth, driven by effective marketing campaigns behind the coated gums and government campaigns to reduce smoking in Western Europe.
- *Lamisil*<sup>AT</sup>, the one week antifungal treatment for athlete's foot, strongly increased net sales based in part on its continued geographic expansion, including its launch in Japan via Sankyo and on its first full year of sales in certain Latin American countries.
- *Benefiber/NovaFibra*, the innovative tasteless, clear and grit free soluble fiber product, continued to gain share and attention in the marketplace as its net sales grew strongly in both Italy and the US.

# **Principal Markets**

In 2004, OTC realized the majority of its net sales in its two principal markets: the US and Europe, including Eastern Europe. In 2002, the OTC Business Unit and Kao Corporation agreed to end their joint

venture to market OTC products in Japan. However, OTC remains committed to expanding its presence in the Japanese market. The following table sets out our 2004 net sales by geographic region.

OTC	Net Sales 2004	
	(\$ millions)	(%)
United States	521	26
Americas (except the United States)	190	10
Europe	1,056	53
Rest of the World	208	11
Total	1,975	100

The OTC business is marked by a high degree of seasonality, with our cough, cold and allergy brands, which include *Triaminic*, *NeoCitran/Theraflu* and *Otrivin*, significantly impacted by the timing and severity of the annual cold and flu season and allergy seasons.

# Production

Our OTC Business Unit has a manufacturing and supply infrastructure comprised of the Business Unit's own plants, strategic third parties and other Novartis Group plants (which are predominantly owned and operated by the Pharmaceuticals Division). The primary OTC plants are located in Lincoln, Nebraska; Nyon, Switzerland; and Humacao, Puerto Rico.

The goal of our supply chain strategy is to produce and distribute high quality products efficiently. Our balance of internal, external and Group sites provides flexibility and predictable sources of supply in the event of capacity constraints or other potential disruptions to supply. The manufacture of our products is heavily regulated, making supply never an absolute certainty. If we or our third party suppliers fail to comply fully with such regulations then there could be a recall or a government-enforced shutdown of production facilities, which in turn could lead to product shortages. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances.

Raw materials for the manufacturing process are purchased from a number of our affiliates and third party suppliers. For the most part, the products and services we procure are not proprietary and are available from a number of suppliers. We often "single-source" supplies, but we have a policy of having at least a second approved and validated supplier registered for most key materials so that substitution is possible. Where practical and beneficial, we have long-term contracts in place on key production inputs. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials.

## Marketing and Sales

We aim to be a leading global participant in fulfilling the needs of patients and consumers for self-medication healthcare. Strong, leading brands, science-based products and in-house marketing and sales organizations are key strengths in pursuing this objective. We distribute our products through various channels, such as pharmacies, food, drug and mass retail outlets.

# Competition

The fundamental trends driving the growth of our OTC business worldwide are increasing pressures on government health funding, changing consumer attitudes towards personal well being, and the rise of a self-care mentality among consumers, and successful switches of prescription products to OTC status, including switches of products which are used for chronic conditions that require patients to consume the product over long periods of time, from months to years. Other companies selling over-the-counter pharmaceutical products include major international corporations with substantial financial and other resources, such as Johnson & Johnson, Sanofi-Aventis, Bayer, GlaxoSmithKline, Pfizer, Procter & Gamble and Wyeth.

#### **Research and Development**

In OTC, the focus of research and development activities is primarily on dermatology, analgesics, cough, cold, allergy, gastrointestinal, minerals, and cardiovascular risk reduction (through smoking cessation programs). OTC also works closely with the Pharmaceuticals Division to evaluate appropriate products that can be switched from prescription to OTC status. The development of line extensions to leverage brand equities is also of high importance. These extensions can take many forms including new flavors, new galenical forms and more consumer-friendly packaging.

The OTC business employs 263 associates in Research and Development with the primary facility located in Nyon, Switzerland. Local country Research and Development organizations largely manage compliance, regulatory needs and medical affairs. In 2004, the OTC Business Unit spent \$84 million in Research and Development, representing 4.3% of net sales.

## Regulation

For OTC products, the regulatory process for bringing a product to market consists of preparing and filing a detailed dossier with the appropriate national or international registration authority and obtaining approval in the US or registration in the EU and the rest of the world. See "Pharmaceuticals—Regulation."

In the US, in addition to the NDA process which is also used to approve prescription pharmaceutical products, an OTC product may be sold if the FDA has determined that the product's active ingredient is generally recognized as safe and effective. FDA makes this determination through a regulatory process known as the OTC Review. In the OTC Review, the FDA establishes, in a series of monographs, the conditions under which particular active ingredients may be recognized as safe and effective for OTC use. Pharmaceutical companies can market products containing these active ingredients without the necessity of filing an NDA and going through its formal approval process, so long as the company complies with the terms of the published monograph.

Most countries also have a regulatory process for switching a particular pharmaceutical product from prescription to OTC status. These processes vary from country to country.

## **Intellectual Property**

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

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

## ANIMAL HEALTH

Our Animal Health Business Unit is a world leader in the research, development, manufacturing and marketing of products and services to save, prolong and improve animal lives. The business of our Animal Health Business Unit is conducted by a number of affiliated companies in 39 countries. As of December 31, 2004, the affiliates of Animal Health employed 2,248 associates worldwide. In 2004, the affiliates of Animal Health achieved consolidated net sales of \$756 million, which represented 3% of the Group's total net sales.

In 2003, we announced a new organizational structure for our Animal Health Business Unit. We have divided our Animal Health business geographically into four Regions—North America, Latin America, Europe and Asia Pacific—and have moved operational responsibilities from our head office to offices in each of these regions, in order to be closer to our markets.

Animal Health researches, develops, manufactures and markets a wide range of products for both companion and farm animals including farmed fish. In 2004, the companion animal segment accounted for 57% of our total Animal Health net sales and the farm animal business, including Vaccines and Aqua Culture Products, accounted for 43%. Our Animal Health products include parasiticides, antimicrobials, vaccines and veterinary pharmaceuticals. Our Animal Health business has a dedicated research and development team, which benefits from synergies with other Novartis businesses, most notably, research in the Pharmaceuticals Division.

We acquired Grand Laboratories Inc. and ImmTech Biologics Inc. in the US in January 2002 for a combined minimum purchase price of \$99 million. The final price may increase depending on whether certain future net sales and other targets are met. These businesses specialize in the development, manufacture and marketing of vaccine products for cattle and pigs. Through these acquisitions we increased the share of vaccines to 8% of the Business Unit's total sales in 2003, strengthened our position in the vaccines market and established our presence in the US farm animal segment.

2004 was characterized by an expansion of our product range, with new products contributing 26% to total annual net sales. This range rejuvenation included new product introductions, geographical extensions, new indications for existing products, and the phase out of non-strategic brands. In parallel, our investments in Marketing & Sales and Research & Development were increased over 2003 to exploit the existing portfolio.

# **Recently Launched Products**

Product	Description	<b>Registration/Launch Status</b>
Companion and Farm Animals		
<i>Adequan</i>	Disease modifying treatment against osteoarthritis in dogs	Launched in the US
Agita	Farm fly control	Launched in Peru, Greece, Portugal and the Middle East
Atopica	Treatment of atopic dermatitis in dogs	Launched in Germany, Netherlands, Ireland and Spain
Deramaxx	First COX-2 inhibitor approved for pain control in dogs	Geographical expansion to Canada
Ethicon	Veterinary suture line	Launched in the US
Fortekor (new palatable presentation)	Congestive Heart Failure in dogs, Chronic Renal Insufficiency in cats	Launched in France, Ireland, Benelux and Italy
Milbemax	Control of intestinal worms in cats and dogs	Launched in Western Europe, Australia, South Africa and Brazil
Vaccines and Aqua Culture Products		
Coxabic	Coccidia vaccine in poultry breeders	Launched in Thailand, South Africa and Argentina
Vaccine line extension in US	Cattle, pig and equine vaccines	2 new products in swine and 1 improved product (ViraShield) were launched in the US
Vaccine line extension in Aqua Culture	Vaccines for salmon and trout	1 vaccine launched in Chile, 1 in Canada, and 1 in Europe

# Key Marketed Products

Products	Description
Companion Animals	
Atopica	Treatment of atopic dermatitis in dogs
<i>Deramaxx</i>	Control of osteoarthritis pain, postoperative orthopedic pain and inflammation in dogs
Ethicon	Veterinary suture line
Fortekor	Treatment of congestive heart failure in dogs and chronic renal insufficiency in cats
Interceptor	Prevention of heartworm and intestinal worms
Milbemax	Control of intestinal worms in cats and dogs
Program	Control of fleas in dogs and cats
Sentinel	Prevention of heartworm and control of fleas and intestinal worms in dogs

# **Farm Animals**

Actatak	Tick growth regulator for beef cattle
Agita	Farm fly control
Clik/Vetrazin	Prevention of blowfly strikes in sheep
Endex	Treatment and control of liver fluke and gastro-intestinal worms in cattle and sheep
Fasinex	Treatment and control of liver flukes in cattle and sheep
Vaccines and Aqua Health	
<i>Apex IHN</i>	Prevention of infectious haematopoietic necrosis
Betamax, Excis	Treatment and control of salmon lice
Bovidec	Prevention of bovine viral diarrhea in cattle
Forte VI	Prevention of infectious salmon anemia and bacterial diseases in farmed salmon
Lipogen Forte	Prevention of bacterial diseases in farmed
Pentium Forte	Prevention of infectious pancreatic necrosis and bacterial diseases in farmed salmon
PneumoStar Myco	Prevention of mycoplasmal pneumonia in swine
<i>Pyceze</i>	Treatment and control of fungal infections in fish and fish eggs

#### **Principal Markets**

Products for companion animals are sold predominantly in North America, the EU, Australia and Japan. In most other countries, sales of farm animal products dominate. The following table sets out 2004 total net sales of our Animal Health products by region:

Animal Health	Net Sales 2004	
	(\$ millions)	(%)
United States	308	41
Americas (except the United States)	83	11
Europe	246	32
Rest of the World	119	16
Total	756	100

Pharmaceutical and biological product sales in all of our main Animal Health businesses (aqua, farm and companion animals) fluctuate seasonally, and can be significantly affected by climatic and economic conditions, and by changing health or reproduction rates of animal populations.

# Production

Approximately 80% of our production volume is manufactured by third parties and Novartis affiliates in other Business Units. Animal Health has production facilities of its own located around the world, with main sites in Wusi Farm, China; Dundee and Braintree (UK); Larchwood, Iowa (US); and Huningue, France.

The manufacture of our products is heavily regulated, making supply never an absolute certainty. If we or our third party suppliers fail to comply fully with such regulations then there could be a governmentenforced shutdown of production facilities, which in turn could lead to product shortages. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances.

We obtain our raw materials from sources around the world. We depend to a large extent on suppliers for the raw materials, intermediates and active ingredients. We make use of long term supply agreements to limit the volatility of prices charged to us for raw materials.

#### Marketing and Sales

Our products are predominantly prescription-only treatments for animals. The major distribution channels are veterinarians and wholesalers of veterinary products. Primary marketing efforts are targeted at veterinarians using such marketing tools as visits by sales representatives, printed materials, direct mail, advertisements and articles in the veterinary special press, our participation at conferences for veterinarians and the organization of special educational events, focusing primarily on key brands and treatment areas. In addition, we engage in general public relations activities, including media advertisements and other direct advertisements of brands, to the extent permitted by law in each country.

#### Competition

Other companies selling veterinary pharmaceutical products for companion and farm animals are Bayer, Elanco (Eli Lilly), Fort Dodge (Wyeth), Intervet (Akzo Nobel), Merial, Pfizer, and Schering-Plough. Most of these companies offer a broad range of products for both companion and farm animals, and their marketing efforts are at a comparable level to ours.

#### **Research and Development**

Novartis Animal Health has dedicated research facilities in Switzerland and Australia for parasiticide. In the US, UK and Canada, we focus on the development of new vaccines for farm animals and farmed fish. In 2004, we stepped up our investment into development projects, devoting \$82 million to research and development. This amount represented 11% of total net sales.

In these efforts, we use high-capacity, in-vitro micro-screening to assess a large number of natural products and synthetic chemicals for bioactivity. Our researchers exploit synergies with other Novartis businesses and also collaborate with external partners to develop veterinary treatments. Drug delivery projects, some in collaboration with external partners, concentrate on our key treatment areas and aim to improve efficacy and ease of use.

We have long-term research commitments totaling \$2 million in the aggregate as of December 31, 2004. We intend to fund these expenditures from internally generated resources.

## Regulation

The registration procedures for animal medicines are similar to those for human medicines. An animal drug application for product registration must be accompanied by extensive data on residue and food safety, target animal safety, environmental effects, efficacy in laboratory and clinical studies as well as information on manufacturing, quality control and labeling.

In the US, animal health products are generally regulated by the FDA's Center for Veterinary Medicine. Certain product categories are regulated by the Environmental Protection Agency (EPA), and vaccines are under the control of the US Department of Agriculture (USDA).

In the EU, veterinary medicinal products need marketing authorization from the competent authority of a member-state (national authorization) or from the EU Commission (community authorization) following either the Centralized Procedure or the MRP. See "Pharmaceuticals—Regulation."

In Japan, veterinary medicinal products are approved by the Ministry of Agriculture, Forestry and Fisheries (MAFF). The application, including supplementary local trial data, is reviewed by the MAFF and a General Investigation Committee, a Special Investigation Committee and a Permanent Investigational Committee before authorization is granted. In addition, any product that is intended for food animals or fish is reviewed by the Food Safety Commission, which was newly established in July 2003, to evaluate the risks to human health of any composition in the products.

#### **Intellectual Property**

Our business is brand-oriented and, therefore, we consider our trademarks to be of utmost value. Trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative.

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

Our business also sells products which are not currently covered by patents. Some of these products have never been patent-protected and others have lost protection due to patent expiry.

#### MEDICAL NUTRITION

Our Medical Nutrition Business Unit is a world leader in the research, development, manufacturing and marketing of enteral and oral nutrition products and devices tailored to the varying needs of patients and healthcare professionals. The business of our Medical Nutrition Business Unit is conducted by a number of affiliated companies in 47 countries. As of December 31, 2004, the affiliates of Medical Nutrition (including Nutrition & Santé) employed 2,948 associates worldwide. In 2004, Medical Nutrition (including Nutrition & Santé) posted \$1.1 billion in net sales, representing 4% of the Group's total net sales.

Our 2004 operating income was significantly affected by a provision of \$51 million with regard to an investigation by the US Department of Justice in the US enteral pump market, including whether certain US federal criminal statutes have been violated. Novartis Nutrition Corporation is currently in the process of negotiating a possible settlement of that portion of the investigation directed against it. See "Item 8. Financial Information—8.A Consolidated Statements and Other Financial Information—8.A.7 Legal Proceedings."

Medical Nutrition is dedicated to maintaining and improving the health and well being of consumers and patients—at home or in health care delivery settings (hospitals, nursing homes and home health care)—by fulfilling their nutritional needs. Working with health care professionals, Medical Nutrition offers high quality medical nutrition products, devices and services ranging from standard to diseasespecific products that improve health and quality of life for all age groups—from pediatrics to geriatrics. This broad range of supplements, tube feedings and food provides essential nutrients for good nutrition when illness or disabilities limit a person's ability to eat a balanced diet.

In February 2004, we completed the acquisition of the adult medical nutrition business of the Bristol-Myers Squibb Company subsidiary Mead Johnson & Company for a total cost of \$385 million. As of December 2004, the integration of this business was substantially completed. This acquisition has created significant opportunities for growth for our Medical Nutrition Business Unit because of existing business and Mead Johnson's complementary brand portfolios and institutional distribution channels, and because the acquisition gave us enhanced access to the retail sector. Key brands acquired through this acquisition are:

- *Boost*, a complete oral nutrition liquid supplement designed to meet the caloric and nutritional requirements of the adult population
- *Isocal*, an isotonic tube-feeding formula used to help patients manage inadequate voluntary oral intake
- Ultracal, a general tube-feeding formula for patients who require dietary fiber
- Nutrament, an energy drink

In July 2003, we secured exclusive global rights for a novel ingredient to treat patients with severe diarrhea. This product was licensed-in from AS Faktor AB, a subsidiary of Lantmannen, Sweden's largest agricultural cooperative.

In June 2003, we acquired Semper Clinical Nutrition, the second largest medical nutrition business in the Scandinavian region. Semper Clinical Nutrition was part of Semper AB, a subsidiary of Arla Foods amba, headquartered in Vidy, Denmark.

In November 2002, we divested our Food & Beverage business, including Ovaltine<sup>®</sup>/Ovomaltine<sup>®</sup>, Caotina<sup>®</sup> and Lacovo<sup>®</sup>, to Associated British Foods plc for \$270 million. The transaction was in furtherance of our strategy of focusing on healthcare and our core pharmaceuticals business. Our remaining Health Food & Slimming and Sports Nutrition businesses were reorganized into a stand-alone unit called Nutrition & Santé. For reporting purposes, this unit's results have been included in the results of the Medical Nutrition Business Unit. We have announced our intention to sell Nutrition & Santé once an attractive bid is received.

# **Key Marketed Products**

*Medical Nutrition.* Our Medical Nutrition Business Unit covers the full spectrum of disease and age specific nutrition. Depending on their condition, patients need specific nutritional support to protect and accelerate their recovery from a disease or surgery. From our comprehensive range of innovative and trusted products for Medical Nutrition, we have created strong and recognizable global brands.

Key brands	Market/segment
Resource	Range of standard and disease-specific oral nutritional supplements
Isosource	A complete range of tube and sip feeds, providing for normal nutritional requirements
Novasource	Nutritionally complete disease or condition-specific enteral feeds
Impact	Oral and enteral products specifically formulated for the critically ill and surgical patients
<i>Compat</i>	Range of standard and specialty devices to deliver tube feeds to the gastrointestinal tract of patients
Optifast	Clinical weight loss program and products
Boost	A complete oral nutrition liquid supplement designed to meet the caloric and nutritional requirements of the adult population
Isocal	An isotonic tube-feeding formula used to help patients manage inadequate voluntary oral intake
Ultracal	A general tube-feeding formula for patients who require dietary fiber
Nutrament	An energy drink

Nutrition & Santé. The stand-alone unit Nutrition & Santé has the following brands:

Key brands	Market/segment	
Health Food & Slimming brands:		
Céréal	A broad range of natural and dietetic foods for health conscious consumers	
Gerblé	A broad range of health food products, many made with wheat germ, which deliver functional benefits	
Gerlinéa	An affordable slimming product range, targeting consumers who wish to remain slim while eating as normally as possible, rather than consumers with a medical weight issue	
Modifast	Slimming products with added vitamins, minerals and proteins	
Dietisa	A product portfolio range including medicinal plants, health foods, dietary supplements and cosmetics, sold mostly in Spain and Portugal	
Pesoforma	Similar product range as Gerlinéa focusing on the Italian market	
Lecinova	Food supplement sold in Italy	
Milical	Meal substitutes range with very low calorie diet and vitamins, minerals & supplements	
Sports Nutrition brands:		
Isostar	Marketed with a niche, scientific strategy to appeal primarily to professional and performance-driven athletes	
Powerplay	Products targeted to bodybuilders, available only in Switzerland, Germany and Austria	
Mineralplus	A recovery powder targeted at athletes who participate in endurance sports, available only in Germany and Austria	

## **Principal Markets**

In 2004, our Medical Nutrition Business Unit (including Nutrition & Santé) realized the majority of its sales in its two principal markets: the US and the EU. With the acquisition and integration of the global adult medical nutrition business of Mead Johnson & Company we have also established a firm base in key Asian markets, most notably Japan. The following table sets out our 2004 net sales by geographic region. The figures include the net sales of Nutrition & Santé.

Medical Nutrition	Net Sales 2	2004
	(\$ millions)	(%)
United States	415	37
Americas (except the United States)	49	4
Europe		50
Rest of the World	94	9
Total	1,121	100

Our products are not subject to seasonality of demand.

#### Production

Our Medical Nutrition Business Unit has a manufacturing and supply infrastructure comprised of the Business Unit's own plants as well as strategic third party suppliers and other Novartis Group plants. The most significant of the dedicated Medical Nutrition plants are located in Minneapolis, Minnesota and Osthofen, Germany.

The goal of our supply chain strategy is to produce high quality products in an efficient manner. The balance of internal and external sites provides flexibility and predictable sources of supply in the event of capacity constraints or other potential disruptions to ongoing supply.

Raw materials for the manufacturing process are purchased from a number of our affiliates and third party suppliers. For the most part, the products and services we procure are not proprietary and are available from a number of suppliers. Where practical and beneficial, we have long-term contracts in place on key production inputs. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials. The manufacture of many of our products is regulated, making supply never an absolute certainty. 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, which in turn could lead to product shortages. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances.

## Marketing and Sales

The majority of the Medical Nutrition Business Unit's net sales (excluding Nutrition & Santé) are to health institutions, such as hospitals, nursing homes, home healthcare providers and group purchasing organizations. As a result of the acquisition of the global adult medical nutrition business of Mead Johnson & Company, we also have a significant level of retail business, principally in the US market. This retail business benefits from a collaboration with the Gerber sales force of our Infant & Baby Business Unit, which markets the *Boost* brand, in the US retail channel. In addition, in the US, outpatient consumers can purchase our products directly through our Walgreens partnership, by means of a toll-free telephone call or the Internet.

## Competition

Novartis Medical Nutrition (excluding Nutrition & Santé) is the second largest medical nutrition company in the world in terms of net sales, with strong positions in the US (second largest) and in Europe (second largest). Other companies selling medical nutrition products are Abbott Ross, Fresenius, Nestlé and Numico.

# **Research and Development**

The Medical Nutrition research and development function is responsible for generating new products and therapies based on the needs of the market. Concepts are developed into prototypes using new and existing ingredients, processes, and packaging. Prototypes are scaled from bench top to pilot plant to production scale. Product attributes are validated through clinical trials under the direction of our Research and Development team, in order to determine whether the product is safe and well-tolerated. Label claims, label designs, and regulatory compliance issues are also addressed. On-going product quality is monitored and improved through specification development, testing, and corrective and preventative action.

In 2004, we invested \$20 million in research and development, which amounted to 2% of net sales.

In July 2003, we announced the globalization of the Medical Nutrition Research and Development function in order to enhance the speed, quality and time to market of our new product innovations across all regions, for both our existing mature product portfolio and our growing disease specific products. Our

global research headquarters has been moved to the US in order to take advantage of the clinical and scientific resources available there, and to help further strengthen our collaboration with the Pharmaceuticals Division.

## Regulation

Foodstuffs are highly regulated in order to protect the public health. The following areas are generally subject to international and national food regulations: development, manufacturing, packaging, quality (food standards, ingredients), safety, labeling and advertising of foods. In the US, the Medical Nutrition Business Unit's products are covered by FDA regulations covering medical foods, dietary supplements and medical devices.

#### **Intellectual Property**

Our Medical Nutrition businesses are brand-oriented and, therefore, we consider our trademarks to be of utmost value. Trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative.

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

## INFANT & BABY

Our Infant & Baby Business Unit is a world leader in the research, development, manufacturing and marketing of foods and products for babies. The business of our Infant & Baby Business Unit is conducted by a number of affiliated companies in more than 50 countries. As of December 31, 2004, the affiliates of Infant & Baby employed 4,385 associates worldwide. In 2004, the affiliates of Infant & Baby achieved consolidated net sales of \$1.4 billion, which represented 5% of the Group's total net sales.

Our Infant & Baby Business Unit is best known for its *Gerber* products which are marketed in the US and in certain other countries. The major contributor to the continued solid performance of the Business Unit is the Gerber business in the US, whose mission is to help parents to raise happy, healthy babies. Business growth in 2004 was driven by such innovations as the conversion of the packaging of pureed products from glass to plastic containers, and the introduction of *Finger Foods* Fruit and Veggie Puffs. Besides nutrition products, the Business Unit offers a wide variety of other products for infants and toddlers, including a baby care line (featuring nursing and feeding aids), wellness products (such as lotions and washes) and life insurance.

Through its "Start Healthy, Stay Healthy" campaign, Gerber continues to proactively address the obesity epidemic in the US. Together with the American Dietetic Association, Gerber introduced a set of dietary guidelines for babies and toddlers under the age of two years. The aim of Start Healthy, Stay Healthy is to provide parents and nutrition professionals with practical advice about the importance of beginning, and how to instill, healthy eating habits early in life.

## **Key Marketed Products**

Globally, our Infant & Baby Business Unit offers more than 200 food products. From 1st FOODS to Graduates, the company's product line covers each phase of child development with diverse flavors and

textures. *Gerber* baby and toddler foods include Cereals, *1st FOODS, 2nd FOODS, 3rd FOODS, Tender Harvest* (organic food), *Finger Foods*, Fruit and Vegetable Juices and *Graduates* toddler food. Gerber's nutrition business began in 1928, in Fremont, Michigan and marked its 75th anniversary in 2003. Gerber began its baby care line in 1960 and now markets more than 350 *Gerber* and NUK<sup>®</sup> branded products. Bottles, teethers, pacifiers, breastfeeding accessories and spill-proof cups are just a few of the products now being distributed to babies and parents around the world.

Continuing its commitment to baby care, *Gerber* introduced a complete line of skin care and health care products in 1999, all designed to help parents raise happy, healthy babies. The skin care products include a full line of washes, lotions and tear-free shampoos. The health care line includes pediatric electrolyte solution, tooth & gum cleanser, diaper rash ointment, gas relief drops and vitamin drops.

Since 1967, our affiliate Gerber Life Insurance Company, has been marketing life insurance protection directly to the consumer. Currently, Gerber Life's *Grow Up* policy is the leading juvenile whole life insurance product distributed in the US and Canada.

In addition, we have licensed the *Gerber* trademark to an unaffiliated company, Gerber Childrenswear, Inc., which sells bibs, apparel, shoes and similar products carrying the trademark. Gerber Childrenswear, Inc. pays royalties to our affiliate, Gerber Products Company, for the use of the trademark.

The major brands and product groups in Infant & Baby are:

Key Brands	Product groups	Main markets
Gerber, Graduates, Lil' Entrees, Tender Harvest, Yukery, 1st FOODS, 2nd FOODS, 3rd FOODS	Baby food	US, Latin America, Europe, Asia
Argos, Fiona, Gerber, Lillo by Gerber, Ninet, NUK <sup>®</sup>	Baby Care	US, Canada, Asia, Latin America
Argos, Capent, Gerber, Ninet	Baby Wellness	US, Latin America
Gerber Life	Insurance	US

### **Recently Launched Products**

In the US, Gerber continued to build on its position as a leader in infant feeding and care with a number of innovations in 2004. In response to consumers' need for convenience, Gerber continued to convert to single serve plastic packages, ideal for out-of-home feeding. In 2004, Gerber improved and changed the 1st FOODS products to this consumer preferred format. Gerber now offers all juices and 1st FOODS and 2nd FOODS fruit purees in single-serve plastic containers. The number of different products packaged in plastic containers will increase in future years. Additionally, the Finger Foods line now offers the popular Fruit and Veggie Puffs, a healthy snack for babies learning to self-feed.

Within the Gerber Care/Wellness business, a number of innovative new products were launched in 2004. The new Premium Feeding System features an innovative manual breast pump, whose funnel replicates the action of a nursing baby's mouth and tongue. Additionally, this line includes a full range of interchangeable cups and bottles to make it easier for mothers to breastfeed. Innovation on the Wellness franchise continued with the introduction of the *Grins & Giggles* line of skincare products, designed to make bath time "fun time" for parents and babies.

#### **Principal Markets**

In 2004, the Infant & Baby Business Unit realized the majority of its sales in its two principal markets: the US and Latin America. The following table sets out our 2004 net sales by geographic region.

Infant & Baby	Net Sales 2	2004
	(\$ millions)	(%)
North America	1,197	83
Latin America	194	14
Europe/Middle East/Africa	35	2
Rest of the World	15	1
Total	1,441	100

Infant & Baby retail sales are not significantly affected by seasonal variations.

#### Production

Key factors in Infant & Baby's successful supply chain strategy include a high efficiency, low cost structure and the mitigation of risks through multiple production sources, both internal and external. Regional sites serve specific markets but are also capable of providing support as needed to other regions in the event of supply disruption. Gerber operates its own production facilities in North America, South America and Eastern Europe for nutrition and Baby Care products. Major production sites are in Fremont, Michigan; Fort Smith, Arkansas; Reedsburg, Wisconsin; Querétaro, Mexico and Rzeszow, Poland. In addition, we contract with 17 companies for the manufacture of our nutrition products, and with 48 companies for our Baby Care products.

The manufacture of most of our products is heavily regulated, making supply never an absolute certainty. 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, which in turn could lead to product shortages. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances. The Baby Care and Wellness franchises tend to utilize suppliers from a wider geographic area.

We often "single-source" supplies, but we have a policy of having at least a second approved and validated supplier registered for most key materials so that substitution is possible. Where practical and beneficial, we have long-term contracts in place on key production inputs. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials.

Raw materials for the manufacturing process are purchased from a number of third party suppliers. For the most part, raw materials for our nutrition products are sourced from within the country of use. Our growers and suppliers are well versed in our strict agricultural requirements and generally have long term relationships with us. We are subject to adverse weather and growing conditions, but mitigate this as much as possible with alternative geographic sourcing areas.

## **Marketing and Sales**

The mission for the Infant and Baby Business Unit is to leverage our brand leadership of trust in helping parents nurture happy, healthy babies into the leading infant and baby brand around the world. In 2004, *Gerber* continued converting glass jars to plastic containers for its nutrition products. This major innovation is a result of consumer data, which clearly indicates the preference for plastic as a better fit for today's active parents and families in the US. *Gerber* will continue to work with the government and

experts in the field of nutrition with respect to its "Start Healthy, Stay Healthy" campaign to help parents start their babies off on a lifetime of healthy eating habits.

Strong brands, product development based on sound nutrition principles, and in-house marketing and sales organizations are some of our key strengths. *Gerber* products are distributed through food, drug and mass merchandiser retail outlets.

#### Competition

Other companies selling infant and baby foods are Del Monte and Beechnut in the US, Nestlé and Heinz in Latin America, Nutricia in Eastern Europe and other regional businesses elsewhere. Other companies selling baby care and wellness products are Johnson & Johnson, Playtex and Avent in the US. There are other companies selling these products located in Latin America and Asia. Another company selling juvenile life insurance policies in the US is Globe Life and Accident Insurance Co., an affiliate of Torchmark Corporation.

## **Research and Development**

The Infant & Baby Business Unit has a Research and Development department which uses a multifaceted approach to deliver consumer innovation by developing new processes, products and packaging for the nutrition, Baby Care and Wellness franchises. Internally developed new processes include *NatureLock*, a patented cooking process for jarred fruits and vegetables. Recent product innovations include *Lil' Entrees*, our nutritious, portable meals for toddlers, and the popular Fruit and Veggie Puffs, a healthy snack for babies learning to self-feed. Packaging innovations include aseptic plastic packaging, which provide additional convenience for consumers.

In addition, *Gerber* Research and Development oversees research regarding the needs of infants and their development. For example, as a part of the "*Start Healthy, Stay Healthy*" campaign, Gerber's Feeding Infants and Toddlers Study (FITS) analyzed the feeding habits and nutrient intake of a cross-sectional, random sample of more than 3,000 US children ranging from 4 to 24 months of age. The results of this Study were published in January 2004, in a special supplement to the Journal of the American Dietetic Association. Gerber commissioned the survey in response to the growing obesity epidemic in the US, in order to better understand eating habits early in life when they are being formed. FITS is the largest scientific study of its kind ever conducted and fills a critical gap in knowledge. The findings have formed the core of the "*Start Healthy, Stay Healthy*" campaign.

In 2004, the Infant & Baby Business Unit invested approximately \$29 million in research and development, representing 2% of Infant & Baby net sales.

## Regulation

Foodstuffs are highly regulated in order to protect the public health. The following areas are generally subject to international and national food regulations: development, manufacturing, packaging, quality (food standards, ingredients), safety, labeling and advertising of foods. Infant foods are regulated by various governmental agencies on a country-by-country basis. There is no global harmony of requirements and regulations. Many countries require food products to be registered in order to document the safety and nutrition of imported food products. *Gerber* food products are specifically designed to meet the nutritional needs of infants and toddlers in the regions where they are sold and to meet or exceed requirements of the local regulatory agencies. These nutritional need standards are determined based on independent, peer-reviewed research, or by studies sanctioned by authorities such as the US Department of Health and Human Services.

In the US, agencies such as the FDA, the USDA, the EPA and the Consumer Product Safety Commission are responsible for providing safety specifications and otherwise regulating our products and ingredients. The FDA and USDA have issued regulations and standards regarding the use of specific ingredients in certain types of food products, including which ingredients are allowed, and at what level, as

well as ingredients that may be required in certain products. In addition, these agencies regulate food product labeling and the claims which can be made regarding food products. Globally, safety of ingredients and products are guided by recommendations from the Codex Alimentarius, a section of the WHO.

## **Intellectual Property**

Our Infant & Baby Business Unit is brand-oriented, with the *Gerber* baby trademark among the most recognized in the world. Therefore, we consider this trademark, as well as others within Infant & Baby, to be of utmost value. Trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative.

Wherever possible our products are protected by patents. Patents may cover products, product formulations, designs, processes, intermediate products or product uses. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

## **CIBA VISION**

CIBA Vision is a world leader in the research, development, manufacturing and marketing of eye care products, specifically soft contact lenses and lens care products. The business of our CIBA Vision Business Unit is conducted by a number of affiliated companies in more than 40 countries. As of December 31, 2004, the affiliates of CIBA Vision employed 5,479 associates worldwide. In 2004, the affiliates of CIBA Vision achieved consolidated net sales of \$1.4 billion, representing 5% of the Group's total net sales.

In 2003 and 2004, CIBA Vision sold to third parties the various assets which made up its former surgical business.

## **Recently Launched Products**

- *O<sub>2</sub>OPTIX*, a new, breathable silicone hydrogel contact lens designed for the health of eyes, received FDA approval and a CE mark in Europe for up to 6 nights extended wear in September 2004. This product permits more than five times the oxygen of the leading contact lens to reach the eye, offering wearers a superior option in reducing corneal oxygen deficiency created by ordinary contact lenses.
- AQuify, 5 Minute Multi-Purpose Solution, a lens care solution that provides a quick way to clean, disinfect and moisturize their contact lenses, was launched in August 2004. This product was previously launched outside of the US under the name SOLO-care AQUA.

# **Key Marketed Products**

The table below sets out the key marketed products in each of CIBA Vision's two principal product segments:

Main Products	Description	
Contact Lenses		
$O_2 OPTIX \dots \dots$	New, breathable silicone hydrogel contact lens with weekly/ monthly replacement	
Focus DAILIES	One-day disposable	
Focus DAILIES Progressives	One-day disposable to correct presbyopia	
Focus DAILIES Toric	One-day disposable to correct astigmatism	
Focus NIGHT&DAY	Extended wear for up to 30 days and nights continuous wear	
Focus Progressives	Corrects presbyopia	
Focus Toric	Corrects astigmatism	
Focus Monthly	Replaced monthly	
<i>Focus</i> 1-2 <i>Week</i>	Replaced every one to two weeks	
Focus 1-2 Week SoftColors	Replaced every one to two weeks; enhances the color of light eyes	
DuraSoft 3 Colors	Conventional cosmetic tinted lenses	
FreshLook Colorblends	Opaque lenses that blend three colors on one lens creating a more natural looking cosmetic tinted lens for dark or light eyes	
FreshLook Colors	Disposable lenses for eye color change	
FreshLook Dimensions	Lenses which enhance the color and appearance of light eyes	
FreshLook Radiance	Lenses for people with light or dark eyes that provide illuminating effects which vary based on a person's natural eye color, skin tone and hair color	
WildEyes	Novelty lenses	
Illusions Opaque	Conventional lenses for changing the color of dark eyes	
Cibasoft	Conventional lenses with handling tint	
Cibasoft Softcolors	Conventional lenses for enhancing the color of light eyes	

Main Products	Description	
Lens Care Products		
AOSept Clear Care/AOSept PLUS .	An enhanced formulation of our leading <i>AOSept</i> hydrogen peroxide disinfectant; the first one-bottle, no-rub lens care solution with no added preservatives in the US	
AQuify/SOLO-care AQUA	Latest generation one-bottle lens care solution formulated with ProVitamin B5 to promote moisture. Product is sold as <i>AQuify</i> in the US. Outside the US, the product is sold under the name <i>SOLO-care AQUA</i> , and each package includes a <i>MicroBlock</i> anti- bacterial contact lens case.	
BLUE Sept/BLUE Vision	One-step hydrogen peroxide lens disinfection system; features blue color indicator	
QuickCARE/InstaCARE	Five-minute disinfectant system	
Pure Eyes	Two-bottle hydrogen peroxide system	
AQuify Lens Drops	Lens drop that replicates natural tears	
Focus Lens Drops	Lens drop for lubricating contact lenses	

# **Principal Markets**

Our principal markets, in terms of 2004 net sales, were North America (US and Canada), Europe and Japan. Sales are not subject to seasonality. The following table sets forth 2004 net sales for CIBA Vision by region:

CIBA Vision	Net Sales 2	2004
	(\$ millions)	(%)
United States	481	34
Americas (except the United States)	67	5
Europe	572	41
Japan	201	14
Rest of the World	91	6
Total	1,412	100

## Production

CIBA Vision has major production facilities in Batam, Indonesia; Duluth, Georgia; Des Plaines, Illinois; Grosswallstadt, Germany; Cidra, Puerto Rico; and Toronto, Canada. The manufacture of our products is heavily regulated, making supply never an absolute certainty. 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, which in turn could lead to product shortages. While we have not experienced material supply interruptions in the past, there can be no assurance that supply will not be interrupted in the future as a result of unforeseen circumstances.

We purchase basic chemical commodity raw materials for our lens products from industrial vendors. These raw materials are then reformulated into the monomers and polymers required to produce contact lenses. Polymer chemistry is one of the innovative elements in our contact lens products. The technology to produce the polymers and monomers is stable and well-defined.

We enter into long-term supply contracts (generally over one to two years) with industrial raw material vendors, which limits volatility. In addition, most raw materials are basic chemical commodities and multiple suppliers are available. Certain lens products use proprietary chemicals that are produced specifically for us and sold exclusively to us. We also use a custom-designed process to synthesize macromonomers, a key raw material needed in contact lens production, which are produced by a contract vendor for a negotiated price.

#### Marketing and Sales

Contact lenses are considered medical devices by regulatory authorities and, therefore, are available only with a prescription from an eye-care professional in most countries. CIBA Vision lenses can be purchased from independent eye care professionals and optical chains. CIBA Vision's lens care products can be found in major drug, food and mass merchandising retail chains in the United States, Europe, Japan and elsewhere. In addition, mail order and Internet sales are becoming increasingly important channels in major markets worldwide.

While eye care professionals have traditionally been CIBA Vision's primary marketing focus, that focus has been shifting toward direct-to-consumer initiatives including free trials and coupons, as well as consumer advertising.

## Competition

#### **Contact Lenses**

Growth in the contact lens market is driven primarily by an increased demand for lenses and an increasingly varied product mix. As consumers move toward frequent replacement lenses, including one-day disposable lenses, demand for lenses is increasing. Additionally, the customer base is expanding with the development of new contact lens options, such as high oxygen transmissibility silicone hydrogels, daily disposable, 30-night continuous wear, toric lenses for astigmatic patients and lenses to correct presbyopia, a condition prevalent among the "Baby Boom" generation. We are the second largest seller of contact lenses in the world, with leading positions in certain contact lens segments such as silicone hydrogel lenses, cosmetic colored lenses, and, in Europe, daily disposable lenses. We believe CIBA Vision now has the broadest product portfolio of any competitor in the industry. Our colored lens technology also creates a strong combination with our other products that should prove attractive to women and teenagers, in particular. Other companies selling contact lenses are Bausch & Lomb, Johnson & Johnson, Cooper and OSI.

#### Lens Care

We expect to increase our presence in the one-bottle lens care market segment with our AQuify/ SOLO-care AQUA brand lens care products and to maintain a leading position in the peroxide category with AOSept Clear Care lens care, which is targeted to wearers of frequent replacement and conventional contact lenses. The peroxide category is a mature market segment and the products will continue to face competitive pressure due to the increasing preference for daily disposable and continuous wear lenses, which require little or no lens care. CIBA Vision is a global leader in the peroxide lens care category with AOSept and AOSEPT Clear Care. Other companies selling lens care products are Alcon, Advanced Medical Optics and Bausch & Lomb.

## **Research and Development**

The research results of other Novartis affiliates provide CIBA Vision with new chemical compounds for future products and access to developments in biotechnology. These resources are complemented by

CIBA Vision's internal research and development capabilities, licensing agreements and joint research and development partnerships with third parties (companies, individuals and universities).

CIBA Vision is continually working to expand its product portfolio through its own dedicated research and development resources as well as through the acquisition of new and innovative technologies. Product development involves the creation of entirely new product offerings as well as line extensions of current products.

For contact lenses our key focus is in three areas: daily disposable contact lenses, silicon hydrogel lenses for continuous or daily wear and an ongoing expansion of our cosmetic and color lenses. In lens care, our development efforts focus on making our lens care solutions more convenient to use, while ensuring that the solutions provide the safety and cleaning power needed to help maintain ocular health.

We invested \$65 million in research and development of eye care products in 2004, representing 4.6% of the Business Unit's net sales.

#### Regulation

Contact lenses, surgical devices and lens care products are regulated as medical devices in the US, the EU and Japan. These jurisdictions each have risk-based classification systems that determine the type of information which must be provided to the local regulators in order to obtain the right to market a product.

In the US, all devices must receive pre-market approval by the FDA. There are two review procedures to gain this pre-market approval: a pre-market application (PMA) and a 510(k) submission. Under a PMA, the manufacturer must submit to the FDA supporting evidence sufficient to prove the safety and effectiveness of the device. The FDA has 180 days to review a PMA. Certain products, however, may qualify for a submission authorized by Section 510(k) of the US Food, Drug and Cosmetic Act. Under this procedure, the manufacturer gives the FDA a pre-market notification that it intends to commence marketing the product, and that it has established that the product is substantially equivalent to another product already on the market. The FDA has 90 days to review a 510(k) submission. In the US, no 30-day extended-wear lenses had previously existed on the market, so we were required to proceed under the PMA procedure. Lens care products generally qualify for 510(k) submission.

In the EU, the "CE" mark is required for all medical devices sold. CIBA Vision affiliates hold a CE mark for the classes of vision care medical devices that they sell. The CE mark allows CIBA Vision to market products upon signing a declaration of conformity with the EU's Medical Device Directive requirements, which CIBA Vision affiliates do for each product sold. In addition, medical device sales in the EU require auditing by a certified third party (a "Notified Body") to ensure that the manufacturer's quality systems are in compliance with the requirements of the ISO 9000 standards. CIBA Vision has two Notified Bodies which routinely audit the company's quality systems.

In Japan, contact lenses are categorized as medical devices and are subject to an approval process similar to that in the US. Although there has been an improvement in the willingness to accept foreign data and a movement toward harmonization of requirements, in order to enter the Japanese market, local clinical trials often are required and local protocols must then be observed. Lens care products for soft lenses take several years to gain approval due to the extensive amount of data and clinical testing required. Saline solutions for hard lenses are unregulated.

#### **Intellectual Property**

Our CIBA Vision business is brand-oriented and, therefore, we consider our trademarks to be of utmost value. Trademarks protect most of our brands in the majority of the markets where these brands are sold, and we vigorously protect these trademarks from infringement. Our most important trademarks are used in a number of countries. Local variations of these international trademarks are employed where legal or linguistic considerations require the use of an alternative. Wherever possible our products are protected by patents. Among other things, patents may cover the products themselves, including contact lenses, polymers and formulations. Patents may also cover the processes and devices for manufacturing a product. Patents may also cover particular uses of a product. It is our policy to seek the broadest possible protection for significant product developments in all major markets.

We have settled all patent litigation against Bausch & Lomb (B&L) regarding patents covering silicone hydrogel long-term wear contact lenses (the "Nicolson" patents). As a result of that settlement, B&L may resume manufacture and sale of its PureVision<sup>™</sup> contact lenses within the US starting in April 2005, when the "Harvey" patent (which was not licensed to B&L) expires. The settlement requires B&L to pay us a royalty on their PureVision<sup>™</sup> sales until 2014 in the US and until 2016 in other countries. As part of the settlement, B&L granted a royalty-free license to CIBA Vision for certain of its patents related to silicone hydrogel technology.

Separately, Johnson & Johnson (J&J) filed suit against CIBA Vision in the US and in Australia in September 2003, and later in New Zealand, claiming that our silicone hydrogel product *Focus NIGHT* & *DAY* infringes a J&J packaging patent, and seeking a declaration that their planned launch of a silicone hydrogel lens product does not infringe the Nicolson patents or that the patents are invalid. These cases are still pending.

## 4.C Organizational Structure

The Novartis Group is a multinational group of companies specializing in the research, development, manufacturing and marketing of innovative healthcare products. 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 note 31 to the consolidated financial statements.

Up to December 31, 2004, the Group was divided operationally into two Divisions: Pharmaceuticals and Consumer Health.

Our Pharmaceuticals Division is organized into two marketing segments - Primary Care and Specialty Medicines - that develop and market branded pharmaceutical products in seven therapeutic areas. The business of the Pharmaceuticals Division is organized into five Business Units: Primary Care, Oncology, Transplantation, Mature Products and Ophthalmics. However, because the Business Units of the Pharmaceuticals Division have common long-term economic perspectives, common customers, common research, development, production and distribution practices, and a common regulatory environment, their financial data is not required to be separately disclosed.

In 2004 the Consumer Health Division was comprised of six Business units: Sandoz generics, OTC self-medication, Animal Health, Medical Nutrition, Infant & Baby and CIBA Vision.

As of January 1, 2005, Sandoz is a separate Division organized as a Retail Generics company which also operates two other businesses, Industrial Products and Biopharmaceuticals. Prior to January 1, 2005, Sandoz was a Business Unit of the Consumer Health Division and was made up of three business franchises: pharmaceuticals, biopharmaceuticals and industrial products.

# 4.D Property, Plants and Equipment

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

It is our policy to own our facilities. A few sites (mainly in the US) are leased under long-term leases. Some of our principal facilities are subject to mortgages and other security interests granted to secure indebtedness to certain financial institutions. As of December 31, 2004, the total amount of indebtedness secured by these facilities was not material to the Group. We believe that our production plants and research facilities are well maintained and generally adequate to meet our needs for the foreseeable future.

The following table sets forth our major production and research facilities.

Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Major Production facilities:		
Pharmaceuticals		
Taboão da Serra, Brazil	539,000 square meters	Capsules, tablets, syrups, suppositories, suspensions, creams, drop solutions, powders
Ringaskiddy, Ireland	532,000 square meters	Drug substances, intermediates
Basel, Switzerland—Klybeck	254,000 square meters	Drug substances, intermediates
Basel, Switzerland—St. Johann	219,000 square meters	Drug substances, intermediates, biotechnology
Basel, Switzerland—Schweizerhalle	237,000 square meters	Drug substances, intermediates
Stein, Switzerland	460,000 square meters	Steriles, tablets, capsules, transdermals
Grimsby, UK	929,000 square meters	Drug substances, intermediates
Suffern, NY	656,000 square meters	Tablets, capsules, transdermals
Horsham, UK	112,000 square meters	Tablets, capsules
Wehr, Germany	165,000 square meters	Tablets, creams, ointments
Torre, Italy	210,000 square meters	Tablets, biotechnology
Barbera, Spain	51,000 square meters	Tablets, capsules
Huningue, France	250,000 square meters (includes Animal Health facilities)	Suppositories, liquids, solutions, suspensions, biotechnology
Kurtkoy, Turkey	109,000 square meters	Tablets, capsules, effervescents
Sasayama, Japan	104,000 square meters	Capsules, tablets, syrups, suppositories, creams, drop solutions, powders
Consumer Health		
Sandoz		
Kundl and Schaftenau, Austria	320,000 square meters (production and R&D facilities)	Biotech products, intermediates, active drug substances, final steps (finished pharmaceuticals)

Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Mengeš, Slovenia	131,000 square meters (production and R&D facilities)	Biotech products and active drug substances
Ljubljana, Slovenia	83,000 square meters (production and R&D facilities)	Broad range of finished dosage forms
Broomfield, CO	60,000 square meters	Broad range of finished dosage forms
Stryków, Poland	20,000 square meters	Broad range of finished dosage forms
Palafolls, Spain	13,000 square meters	Injectable products
Kalwe, India	10,000 square meters	Broad range of finished dosage forms
Boucherville, Canada	4,600 square meters	Injectable products
ОТС		
Lincoln, NE	44,870 square meters	Liquids, creams and tablets
Nyon, Switzerland	14,700 square meters (production and R&D facilities)	Liquids and creams
Humacao, Puerto Rico	8,000 square meters	Sugar coated tablets, small chocolate tablets, packaging of softgels
Animal Health		
Wusi Farm, China	42,000 square meters	Insecticides, antibacterials, acaricides, powders
Dundee, UK	34,000 square meters	Packaging, formulation liquids, solids, creams, sterile filling
Larchwood, IA	29,700 square meters (production and R&D facilities)	Veterinary immunologicals
Braintree, UK	10,000 square meters	Veterinary immunologicals
Huningue, France	6,000 square meters	Formulation and packaging of tablets, creams, ointments, suspensions and liquids
Medical Nutrition		
Minneapolis, MN	33,500 square meters (production and R&D facilities)	Medical nutrition products

Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Osthofen, Germany	17,000 square meters (production and R&D facilities)	Medical nutrition and Nutrition & Santé products
Infant & Baby		
Fremont, MI	107,000 square meters (production and R&D facilities)	<i>Gerber</i> jarred baby food, fruit and vegetable juices, dry boxed cereal
Fort Smith, AR	80,451 square meters	<i>Gerber</i> jarred baby food, dry cereal
Querétaro, Mexico	205,000 square meters	<i>Gerber</i> jarred baby food, fruit and vegetable juices, dry canned and bagged cereal
Reedsburg, WI	30,000 square meters	Baby Care products; spill- proof cups, bottles, nipples, breast pads, pacifiers, overcaps
Campo Grande, Brazil	89,000 square meters	Baby Care products; spill- proof cups, bottles, nipples, breast pads, pacifiers, overcaps
Rzeszow, Poland	45,000 square meters	Gerber baby food, fruit juice
CIBA Vision		
Pulau Batam, Indonesia	19,000 square meters	Contact lenses
Duluth, GA	34,000 square meters	Contact lenses
Des Plaines, IL	27,400 square meters	Freshlook product line
Grosswallstadt, Germany	23,000 square meters	Contact lenses
Cidra, Puerto Rico	6,100 square meters	Contact lenses
Toronto, Canada	14,500 square meters	Lens care products
Major Research and Development Facilities:		
Pharmaceuticals		
East Hanover, NJ	177,398 square meters	General pharmaceutical products
Cambridge, MA	75,300 square meters	General pharmaceutical products
Basel, Switzerland—Klybeck	140,000 square meters	General pharmaceutical products

Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Basel, Switzerland—St. Johann	150,000 square meters	General pharmaceutical products
Vienna, Austria	39,000 square meters	Dermatology
Tsukuba, Japan	20,600 square meters	General pharmaceutical products
Horsham and London, UK	37,700 square meters	Respiratory and nervous system diseases
Consumer Health		
Sandoz		
Kundl and Schaftenau, Austria	320,000 square meters total area (production and R&D facilities)	Biotech processes, innovations in antibiotic technologies
Mengeš, Slovenia	131,000 square meters (production and R&D facilities)	Biotech products and active drug substances
Ljubljana, Slovenia	83,000 square meters (production and R&D facilities)	Broad range of finished dosage forms
Kolshet, India	5,000 square meters	Generic pharmaceuticals
Dayton, NJ	29,000 square meters	Broad range of finished dosage forms
Boucherville, Canada	4,377 square meters	Injectable products
ОТС		
Lincoln, NE	44,870 square meters	Liquids, creams and tablets
Nyon, Switzerland	14,700 square meters (production and R&D facilities)	Over-the-counter medicine products
Animal Health		
St. Aubin, Switzerland	26,000 square meters	Parasiticides
Larchwood, IA	29,700 square meters (production and R&D facilities)	Veterinary immunologicals development
Yarandoo, Australia	3,250 square meters	Animal Health products
Medical Nutrition		
Minneapolis, MN	33,500 square meters (production and R&D facilities)	Medical nutrition products

Size of Site (in square meters)	<b>Major Activity</b>		
17,000 square meters (production and R&D facilities)	Medical nutrition and Nutrition & Santé products		
107,000 square meters (production and R&D facilities)	Baby food products		
9,000 square meters	Vision-related medical devices		
	17,000 square meters (production and R&D facilities) 107,000 square meters (production and R&D facilities)		

In 2004, we completed the expansion of the Novartis Institutes for BioMedical Research, Inc. (NIBRI) facility in Cambridge, Massachusetts., This new research facility contains a total of 75,300 square meters of laboratory and office space. It will house over 800 scientists and technology experts, and approximately 1,000 employees in total. To date, we have invested approximately \$503 million in property, plant and equipment at this new facility.

Progress is being made in the long-term redevelopment of our St. Johann headquarters site in Basel. This project, called "Campus," was started in 2001 with the aim of transforming the site into a knowledge location with a primary emphasis on research activities and international corporate functions. Research now accounts for a greater proportion of our activities at the site, and these changes need to be reflected since it is currently designed primarily for pharmaceuticals production. For the first phase of the Campus Project, which is planned through 2008, a total of approximately \$577 million (CHF 655 million) has been approved by the Board of Directors. A second phase is also planned. Costs related to this project will depend on the pace of construction.

In 2004, we announced plans to build a new pharmaceuticals production facility in Singapore, providing additional needed capacity within our global manufacturing network. The facility will produce tablets for the global market, and is expected to begin operations in 2007. We will invest approximately \$180 million in the project, which includes building and equipment, leasing of land, a distribution center and start-up costs.

We also announced plans for an approximately \$95 million (EUR 70 million) overall investment in a new generics production and logistics facility in Stryków, Poland. Operated by Lek, a Sandoz company, the 25,000-meter complex will include an administration building, laboratories, production lines and storage centers.

Also in 2004, we sold our pharmaceuticals production site in Hettlingen, Switzerland, to the French company Bernard Fraisse Group.

#### **Environmental Matters**

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

We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, use and disposal of materials, including the discharge of pollutants into the environment. In the normal course of our business, we are exposed to risks relating to possible releases of hazardous substances into the environment which could cause environmental or property damage or personal injuries, and which

could require remediation of contaminated soil and groundwater. Under certain laws, we may be required to remediate contamination at certain of our properties regardless of whether the contamination was caused by us, or by previous occupants of the property.

We believe that we are in substantial compliance with environmental, health and safety requirements applicable to us. We are committed to providing safe and environmentally sound workplaces that will not adversely affect the health or environment of employees or the communities in which we operate. We believe that we have obtained all material environmental permits required for the operation of our facilities as well as all material authorizations required for the products produced by us. We believe that we are not currently subject to liabilities for non-compliance with applicable environmental, health and safety laws that would materially and adversely affect our business, financial condition or results of operations. However, there is a risk that legislation enacted in the future could create liabilities for past activities undertaken in compliance with then-current laws and regulations or that there is environmental or other damage of which we are not aware.

In recent years, the operations of all companies have become subject to increasingly stringent legislation and regulation related to occupational safety and health, product registration and environmental protection. Such legislation and regulations are complex and constantly changing, and there can be no assurance that future changes in laws or regulations would not require us to install additional controls for certain of our emission sources, to undertake changes in our manufacturing processes or to remediate soil or groundwater contamination at facilities where such clean-up is not currently required. Some of our facilities are over 50 years old, and there may be soil and groundwater contamination at such facilities. However, based on current information, we do not believe that expenditures related to such possible contamination, beyond those already accrued, will be significant.

Our expenditures related to capital investments for environmental, health and safety compliance measures were approximately \$79 million in 2004 (\$10 million for environment), \$88 million in 2003 (\$12 million for environment) and \$42 million in 2002 (\$7 million for environment). While we cannot predict with certainty our aggregate capital environmental investments in 2005, based on current information and existing assets, we estimate that such aggregate expenditures will be comparable to the 2004 figure.

It is difficult to estimate the future costs of environmental protection and remediation because of many uncertainties, including uncertainties about the state of laws, regulations and information related to individual locations and sites. However, given our experience to date regarding environmental matters and the facts currently known, we believe that compliance with existing and known national and local environmental laws and regulations will not have a material effect on our financial condition, but could be material to our results of operations in a given period.

## Item 5. Operating and Financial Review and Prospects

# 5.A Operating Results

The following operating and financial review and prospects should be read in conjunction with our consolidated financial statements included in this Form 20-F. The consolidated financial statements and the financial information discussed below have been prepared in accordance with International Financial Reporting Standards (IFRS). Please see "Item 18. Financial Statements—note 32" for a discussion of the significant differences between IFRS and US Generally Accepted Accounting Principles (US GAAP).

#### Overview

We are a world leader both in sales and in innovation in our continuing core businesses: pharmaceuticals and consumer health, which includes generics, OTC self-medication, animal health, medical nutrition, infant and baby foods and products, and eyecare products, with global net sales of \$28.2 billion in 2004. We aim to hold a leadership position in all of our businesses.

Novartis AG was formed in 1996 out of a merger of two global participants in the pharmaceutical and agrochemical industries, Sandoz AG and CIBA-Geigy AG. Accounting for the merger under IFRS was based on a uniting of interests and therefore did not result in any goodwill nor in any goodwill amortization. Under US GAAP, the merger is accounted for as a purchase of CIBA-Geigy AG by Sandoz AG. For a discussion of the significant differences between IFRS and US GAAP purchase accounting, see "Item 18. Financial Statements—note 32."

In November 2000, we spun off our Crop Protection and Seeds businesses and merged them with AstraZeneca's Zeneca Agrochemicals to create Syngenta AG, a public company.

## Factors affecting results

The global health care market is growing rapidly due to, among other reasons, the aging population in developed countries, unmet needs in many therapeutic areas (such as cancer and cardiovascular disease), the adoption of more industrialized lifestyles in emerging economies, and increased consumer demand fueled by broad and rapid access to information. At the same time, the health care industry is under increasing pressure to reduce prices as payors in the public and private sectors seek to curb rising health care costs.

Our revenues are directly related to our ability to identify and develop high potential products and to bring them to market quickly and effectively. Efficient and productive research and development is crucial in this environment since Novartis, like its competitors, searches for efficacious and cost-efficient pharmaceutical solutions to health problems. The resource requirements to access the full range of new technologies has been one reason for industry consolidation, as well as the increase in collaborations between leading companies and niche players at the forefront of their particular technology areas. The growth in new technology, particularly genomics, is expected to have a fundamental impact on the pharmaceutical industry and upon our future development.

Competition in the generic pharmaceutical market continues to intensify as the pharmaceutical industry adjusts to increased pressures to contain health care costs. Brand-name companies have taken aggressive steps to counter the growth of the generics industry. In particular, brand-name companies continue to sell their products to the generic market directly by acquiring or forming strategic alliances with generic pharmaceutical companies. No significant regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. In addition, brand-name companies continually seek new ways to delay generic introduction and to decrease the impact of generic competition. These efforts by the brand-name pharmaceutical industry have had, and likely will continue to have, a negative effect on the results of operations of our Sandoz Division.

Under US law the Food and Drug Administration (FDA) must award 180 days of market exclusivity to the first generic manufacturer who challenges the patent of a branded product. However, recent changes in the Hatch-Waxman Act may affect the availability of this market exclusivity in the future. The new amendments now require generic applicants to launch their products within certain time frames or risk losing the marketing exclusivity that they had gained through being a first-to-file applicant.

At times we seek approval to market generic products before the expiration of patents held by others for those products, based upon our belief that such patents are invalid, unenforceable, or would not be infringed by our products. As a result, Novartis often faces significant patent litigation. If we are unsuccessful in such litigation, then its ability to launch new products will be substantially limited. In addition, depending upon a complex analysis of a variety of legal and commercial factors, we may, in certain circumstances, elect to market a generic product even though litigation is still pending. This could be before any court decision or while an appeal of a lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages if the final court decision is adverse to us.

In addition, competitive conditions have intensified as a result of regulation, price reductions, reference prices, parallel imports, higher patient co-payments and increased pressure on physicians to

reduce their prescribing of prescription medicines. Pressure on our Pharmaceutical Division and other pharmaceutical companies to lower prices is expected to increase primarily due to government initiatives to reduce patient reimbursement, restrict prescribing levels, increase the use of generics and impose overall price cuts. The introduction of technologically innovative products and devices by competitors and growing product distribution and importation anomalies, mainly in the EU, pose additional challenges. Exchange rate exposure also affects our results since we have both sales and costs in many currencies other than the US dollar, our reporting currency. This gives rise to both transaction exposure in subsidiary financial statements due to foreign currency denominated transactions and translation exposure from converting non-US dollar subsidiary results and balance sheets into the our US dollar consolidated financial statements. Our results have not been significantly affected by inflation.

# **Critical Accounting Policies**

Our principal accounting policies are set out in note 1 of the Group's consolidated financial statements and conform to International Financial Reporting Standards (IFRS). Significant judgments and estimates are used in the preparation of the consolidated financial statements which, to the extent that actual outcomes and results may differ from these assumptions and estimates, could affect the accounting in the areas described in this section.

## Revenue

Revenue is recognized when title and risk of loss for the products is transferred to the customer. Accruals for US Medicaid and similar rebates in the US and other countries, chargebacks, estimated returns, customer rebates and discounts are established concurrently with the recognition of revenue. Accordingly, sales are reported net of these allowances which, since they are estimated, may not fully reflect the final outcome.

The following briefly describes the nature of each accrual and how such accruals are estimated with specific reference to the US practices:

- The US Medicaid program, established under Title XIX of the Social Security Act, is a state administered program, using state and federal funds, to provide assistance to certain vulnerable and needy individuals and families. In 1990, the Medicaid Drug Rebate Program was established to reduce state and federal expenditures for prescription drugs. Under the rebate program, we have signed an agreement to provide a rebate on drugs paid for by a state. Provisions for estimating Medicaid Rebates are calculated using a combination of historical experience, product and population growth, anticipated price increases, the impact of contracting strategies and specific terms in the individual state agreements. These provisions are adjusted based upon the established refiling process with the individual states.
- We participate in prescription drug savings programs that offer savings to patients that are eligible Medicare participants. These savings vary based on a patient's current drug coverage and personal income levels.
- We have arrangements with certain parties establishing discounted prices for our products. A chargeback represents the difference between the invoice price to the wholesaler and the indirect customer's contract discount price. Provisions for estimating chargebacks are calculated using a combination of historical experience, product growth rates and the specific terms in each agreement.
- Where there is a historical experience of agreeing to customers returns, we record a reserve for estimated sales returns by applying historical experience of customer returns to the amounts invoiced and the amount of returned product to be destroyed versus product that can be placed back in inventory for resale.

- Our policy relating to supply of pharmaceuticals products is to maintain inventories on a consistent level from year to year based on the pattern of consumption. A process exists at Novartis Pharmaceuticals Corporation to monitor on a monthly basis inventory levels at wholesalers based on the gross sales volume, prescription volumes based on IMS data and information received from the key wholesalers. Based on this information, the inventories on hand at wholesalers and other distribution channels in the US are less than one month at December 31, 2004. Similar processes exist in the Sandoz generics and OTC businesses. We believe the third party data sources of information are sufficiently reliable, however their accuracy cannot be verified.
- Customer rebates are offered to key managed care, group purchasing organizations and other direct and indirect customers to sustain and increase our product market share. These rebate programs provide that the customer receive a rebate after attaining certain performance parameters relating to product purchases, formulary status and/or pre-established market share milestones relative to competitors. Since rebates are contractually agreed upon, rebates are estimated based on the specific terms in each agreement, historical experience and product growth rates.
- Cash discounts are offered to customers to encourage prompt payment that is accrued at the time of invoicing.
- Shelf-stock adjustments are granted to customers based on the existing inventory of a customer following decreases in the invoice or contract price of the related product. Provisions for shelf-stock adjustments are determined at the time of the price decline or at the point of sale if a price decline is reasonably estimable and are based on estimated inventory levels.
- Historical data has been adjusted, where applicable, to give effect to subsequent events, including, primarily, the effect of increased turnover on such provisions.

The US market has the most complex arrangements in this area. The following tables show the extent of rebates made and payment experiences in the US in 2004 for our key subsidiaries affected, which are Novartis Pharmaceuticals Corporation, Sandoz Inc. and Novartis Consumer Health Inc. (OTC):

			Income State	Income Statement charge		
	January 1, 2004	Payments	Adjustments of prior years	Current year	December 31, 2004	
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	
Medicaid rebates & credits including prescription drug						
saving cards Managed Health Care rebates & other	247	(562)	(15)	639	309	
rebates	251	(565)	(34)	572	224	
Chargebacks	162	(819)	(1)	799	141	
Sales Returns	190	(127)	(1)	103	165	
Other deductions	91	(351)	(1)	345	84	
Total	941	(2,424)	(52)	2,458	923	

## Accruals for Revenue Deductions in the US

#### Gross to Net sales reconciliation in the US

	2004 (\$ millions)	% of gross sales
Gross Sales subject to deductions	11,028	<u>100</u>
Medicaid & Medicare rebates and prescription drug saving cards	(624)	(6)
Managed Health Care rebates & other rebates	(538)	(5)
Chargebacks including Hospital chargebacks	(800)	(7)
Sales Returns	(115)	(1)
Other deductions	(355)	(3)
Total Gross to Net sales adjustments <sup>(1)</sup>	(2,432)	(22)
Net sales	8,596	78

<sup>(1)</sup> \$26 million was charged directly to the Income Statement without being recorded in the Revenue Deduction Accruals.

## Impairment of long-lived assets

Long-lived assets are regularly reviewed for impairment, including identifiable intangibles and goodwill, whenever events or changes in circumstance indicate that the balance sheet carrying amount of the asset may not be recoverable. In order to assess if there is any impairment, estimates are made of the future cash flows expected to result from the use of the asset and its eventual disposal. If the balance sheet carrying amount of the asset is more than the higher of its value in use to us or its anticipated net selling price, an impairment loss for the difference is recognized. Actual outcomes could vary significantly from such estimates of discounted future cash flows. Factors such as changes in the planned use of buildings, machinery or equipment, or closing of facilities or lower than anticipated sales for products with capitalized rights could result in shortened useful lives or impairment. Additional information on the US GAAP carrying values of trademarks, product and marketing rights is presented in note 32 m (xi).

#### Fair value or impairments adjustments on financial instruments

We have extensive investments in marketable securities and have significant derivative financial instrument positions that are mainly, but not exclusively, held for hedging underlying positions. Depending on the development of equity and derivative markets, it may be necessary to recognize impairments on the marketable securities or losses on the derivative positions in our consolidated income statement.

## Investments in associated companies

We have investments in associated companies (defined generally as investments of between 20% and 50% of a company's voting shares) that are accounted for by using the equity method. Due to the various estimates that have been made in applying the equity method, the amounts recorded in the consolidated financial statements in respect of Roche Holding AG and Chiron Corporation may require adjustments in the following year after more financial and other information becomes publicly available.

## **Retirement benefit plans**

We sponsor pension and other retirement plans in various forms covering employees who meet eligibility requirements. These plans cover the majority of our employees. Several statistical and other factors that attempt to anticipate future events are used in calculating the expense and liability related to the plans. These factors include assumptions about the discount rate, expected return on plan assets and rate of future compensation increases, as determined by our management within certain guidelines. In addition, our actuarial consultants use statistical information such as withdrawal and mortality rates for their estimates. The actuarial assumptions used may differ materially from actual results due to changing market and economic conditions, higher or lower withdrawal rates or longer or shorter life spans of participants. These differences may result in a significant impact to the amount of pension income or expense recorded in future years.

### **Environmental provisions**

We have provisions for environmental remediation costs. The material components of the environmental provisions consist of costs to fully clean and refurbish contaminated sites and to treat and contain contamination at sites where the environmental exposure is less severe. Future remediation expenses are affected by a number of uncertainties that include, but are not limited to, the method and extent of remediation, the percentage of waste material attributable to us at the remediation sites relative to that attributable to other parties, and the financial capabilities of the other potentially responsible parties. We believe that our total provisions for environmental matters are adequate based upon currently available information. However, given the inherent difficulties in estimating liabilities in this area, we cannot guarantee that additional costs will not be incurred beyond the amounts accrued. The effect of resolution of environmental matters on results of operations cannot be predicted due to uncertainty concerning both the amount and the timing of future expenditures and the results of future operations. Our management believes that such additional amounts, if any, would not be material to our financial condition but could be material to future results of operations in a given period.

## Litigation provisions

A number of our subsidiaries are subject to litigation arising out of the normal conduct of their businesses, as a result of which claims could be made against them which might not be covered by existing provisions or by insurance. Our management believes that the outcomes of such actions, if any, would not be material to our financial condition but could be material to future results of operations in a given period.

## Goodwill under US GAAP

In 2004, according to IFRS we continued to amortize goodwill even though for US GAAP purposes we ceased to amortize goodwill in accordance with Statement of Financial Accounting Standards ("SFAS") No. 142 *Goodwill and Other Intangible Assets*. SFAS 142 requires us to perform an annual review of our US GAAP goodwill for impairment. Based on this annual review, we recognize impairment losses if necessary. In particular, just under US GAAP, we have goodwill relating to Gerber Products with a carrying amount of \$2.9 billion at December 31, 2004. As required, we performed our annual impairment test of goodwill in 2004, which did not require us to record an impairment charge. The process of evaluating goodwill involves making adjustments and estimates relating to the projection and discounting of future cash flows. This evaluation is sensitive to changes in the discount rate. An increase to discount rates is likely to result in a significant impairment charge under US GAAP.

## Accounting developments

The International Accounting Standards Board (IASB) has and will continue to critically examine current International Financial Reporting Standards (IFRS) with a view toward increasing international harmonization of accounting rules. This process of amendment and convergence of worldwide accounting rules resulted in significant amendments to the existing rules from January 1, 2005 in such areas as the accounting for share-based compensation, goodwill and intangibles, marketable securities and derivative financial instruments as well as the classification of certain income statement and balance sheet positions. These are discussed in more detail in note 32 m (xii) of our consolidated financial statements.

# Compliance with Sarbanes-Oxley Act of 2002 on internal control over financial reporting

In line with domestic US registrants with the Securities and Exchange Commission (SEC), we have successfully completed our assessment of internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act in 2004 and obtained on this assessment a report from our independent auditors. No material weaknesses were revealed by this extensive review of the internal control over financial reporting. Please see Item 15—"Controls and Procedures" for a more detailed discussion of our assessment.

# **Results of Operations**

The following table sets forth selected income statement data for each of the periods indicated.

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Net sales to third parties			
Pharmaceuticals	18,497	16,020	13,528
Sandoz	3,045	2,906	1,817
ОТС	1,975	1,772	1,521
Animal Health	756	682	623
Medical Nutrition	1,121	815	711
Infant & Baby	1,441	1,361	1,333
CIBA Vision	1,412	1,308	1,135
Consumer Health—ongoing	9,750	8,844	7,140
Divested Health & Functional Food activities			209
Consumer Health	9,750	8,844	7,349
Group net sales	28,247	24,864	20,877
Net sales	28,247	24,864	20,877
Cost of Goods Sold	(6,625)	(5,894)	(4,994)
Marketing & Sales	(8,873)	(7,854)	(6,737)
Research & Development	(4,207)	(3,756)	(2,843)
General & Administration	(1,540)	(1,381)	(1,146)
Other income & expense	(463)	(90)	(65)
Group Operating income	6,539	5,889	5,092
Operating income by Division/Business Unit			
Pharmaceuticals	5,253	4,423	3,891
Sandoz	235	473	265
ОТС	351	309	240
Animal Health	78	88	92
Medical Nutrition	32	82	4
Infant & Baby	274	254	227
CIBA Vision	236	153	118
Divisional Management	(25)	(39)	
Consumer Health—ongoing	1,181	1,320	946
Divested Health & Functional Food activities			140
Consumer Health	1,181	1,320	1,086
Corporate income, net	105	146	115
Operating income	6,539	5,889	5,092
Result from associated companies	142	(200)	(7)
Financial income, net	227	379	613
Taxes	(1,126)	(1,008)	(959)
Minority interests	(15)	(44)	(14)
Net income	5,767	5,016	4,725

## 2004 Compared to 2003

The following compares our results in the year ended December 31, 2004 to those of the year ended December 31, 2003. Our analysis is divided as follows:

- 1. Overview
- 2. Net Sales by Division and Business Unit
- 3. Operating Expenses
- 4. Operating Income by Division and Business Unit
- 5. Net Income

#### 1. Overview

Our net sales rose 14% (+9% in local currencies, or lc) to \$28.2 billion in 2004 as strong results were recorded in both Pharmaceuticals as well as Consumer Health, where OTC and Medical Nutrition offset lower net sales growth in the Sandoz generics business. Volume increases were the primary growth driver contributing 8 percentage points to our net sales growth. Currency benefits added 5 percentage points, while acquisitions added one percentage point and price increases across the Group were insignificant (<1%). Pharmaceuticals accounted for 65% of our total net sales and Consumer Health 35%, while the US accounted for 40% of our total net sales, Europe for 36% and the rest of the world for 24%.

Operating income advanced 11%, supported by strong volume expansion of leading Pharmaceutical products. Most categories of functional expenses had a positive impact on the operating margin. Cost of Goods Sold (COGS) rose 12% but declined as a percentage of net sales by 0.2 percentage points to 23.5% owing mainly to efficiency gains and better product mix in Pharmaceuticals. Marketing & Sales fell 0.2 percentage points to 31.4% of net sales based primarily on sales-force productivity improvements, while Research & Development declined 0.2 percentage points to 14.9% of net sales following fewer upfront development costs. General & Administrative expenses also rose at a slower pace than net sales, accounting for 5.5% of net sales. Our operating margin, however, fell 0.6 percentage points to 23.1% from 23.7% in 2003 due mainly to one-time charges in Sandoz, Medical Nutrition and Animal Health that led to higher Other Operating Expenses.

The main factors contributing to higher Other Operating Expenses were substantially lower Corporate pension income of \$102 million; increased restructuring charges and related impairments on property, plant & equipment in the Sandoz generics business of \$37 million, a reduction of \$171 million in hedging gains on anticipated intragroup sales and lower product divestment gains principally due to the \$178 million *Fioricet/Fiorinal* gain recorded in 2003. Overall, the strong organic growth and positive contribution this year from associated companies resulted in net income expanding 15% to \$5.8 billion. Earnings per share rose 16%, slightly more than net income due to the impact of the share buy-back program, to \$2.36 per share in 2004 from \$2.03 per share in 2003.

# 2. Net Sales by Division and Business Unit

The following table sets forth selected net sales data for each of the periods indicated.

	Year ended l	December 31,		Change in local	
	2004 2003		Change in \$	currencies	
	(\$ millions)	(\$ millions)	(%)	(%)	
Net sales					
Pharmaceuticals	18,497	16,020	15	<u>10</u>	
Sandoz	3,045	2,906	5	(1)	
OTC	1,975	1,772	11	5	
Animal Health	756	682	11	5	
Medical Nutrition	1,121	815	38	31	
Infant & Baby	1,441	1,361	6	6	
CIBA Vision	1,412	1,308	8	2	
Consumer Health	9,750	8,844	10	5	
Total	28,247	24,864	14	9	

As discussed in the Critical Accounting Policies Section, the US market has the most complex arrangements in the area of deductions from gross sales to arrive at net sales, which is the starting point for all our discussions on our sales developments. The following table shows the extent of rebates made in the US for our key subsidiaries affected, which are Novartis Pharmaceuticals Corporation, Sandoz Inc. and Novartis Consumer Health Inc. (OTC):

# Gross to Net sales reconciliation in the US

	2004	% of gross sales	2003	% of gross sales
Gross Sales subject to deductions	(\$ millions) 11,028	100	(\$ millions) 10,429	100
Medicaid & Medicare rebates and prescription				
drug saving cards	(624)	(6)	(390)	(4)
Managed Health Care rebates & other rebates	(538)	(5)	(557)	(5)
Chargebacks including Hospital chargebacks	(800)	(7)	(1,008)	(10)
Sales Returns	(115)	(1)	(184)	(2)
Other deductions	(355)	(3)	(411)	(4)
Total Gross to Net sales adjustments $^{(1)}$	(2,432)	(22)	(2,550)	(25)
Net sales	8,596	78	7,879	75

(1) \$26 million was charged directly to the Income Statement without being recorded in the Revenue Deduction Accruals (2003: \$38 million). The principal reason for the changes in the percentage deductions from gross sales are the following:

The 2 percentage points increase in Medicaid & Medicare rebates and prescription drug saving cards is mainly due to an increase in Consumer Price Index penalties resulting from 2004 pricing actions, additional state supplemental programs and an increase in the growth of the Medicaid population.

The Consumer Price Index (CPI) penalties represent the increase in Medicaid rebates due to Novartis price increases in a given year exceeding the U.S. inflation rate, which is calculated on a cumulative basis over the life of each product.

The 3 percentage points decrease of Chargebacks including Hospital chargebacks is principally a reflection of the lower gross sales in 2004 compared to 2003 of Sandoz Inc.

# Pharmaceuticals Division

The Pharmaceuticals Division, bolstered by the five blockbusters *Diovan, Gleevec/Glivec, Lamisil, Zometa and Neoral*, reported a net sales increase of 15% (+10% lc) amid outstanding performances from top-selling prescription drugs in both the Primary Care and Specialty Medicines portfolios and above-average growth in several key markets. Most therapeutic areas expanded at double-digit rates in US dollars. Volume expansion contributed 10 percentage points, while currency benefits added five percentage points. Price changes had little impact.

Total net sales of strategic franchise products (Pharmaceutical net sales excluding mature products) rose 21% (+16% lc) to \$15.4 billion as seven of the top ten drugs delivered robust double-digit net sales increases. Primary Care (excluding Mature Products) reported a net sales increase of 21% (+17% lc), led by the strong cardiovascular franchise (+21%, +17% lc) with the ongoing growth of the antihypertensive medicines *Diovan*, the No. 1 angiotensin receptor blocker (ARB) and No. 2 branded antihypertensive worldwide, and *Lotrel*, the No. 1 branded US combination high blood pressure treatment. Net sales in Specialty Medicines, which includes our activities in Oncology, Transplantation & Immunology, and Ophthalmics, rose 22% (+15% lc) to \$6.1 billion and accounted for 33% of Pharmaceuticals net sales versus 31% in 2003. The Oncology franchise reported a 28% (+22% lc) advance, ranking as one of the fastest-growing businesses in its sector. The key oncology drugs *Gleevec/Glivec, Zometa* and *Femara* delivered dynamic growth as new data was presented during 2004 that continued to demonstrate benefits to patients. Mature Products reported a 7% decline (-12% lc) in net sales to \$3.1 billion.

# Primary Care

- *Diovan* (+28%; +22% lc; +20% US) maintained a strong growth rate in 2004 in the US and worldwide with net sales exceeding \$3.0 billion, reaffirming its position as the world's leading ARB and one of the fastest-growing branded hypertension medicines. In the US, *Diovan* reached 2.6% of the US broad antihypertension market segment and 38.5% of the ARB therapeutic category (IMS Health data as of December 2004), which is expected to remain one of the most dynamic pharmaceutical categories in the coming years. Net sales growth has been driven primarily by data from recent successful outcome trials, the global rollout of more effective doses and the recent launch of our sponsored hypertension awareness program in the US. We recently received an approvable letter from the US Food and Drug Administration (FDA) for *Diovan* to treat high-risk heart attack patients, an indication already approved in 27 countries, including the UK. Approval is pending further discussions with the FDA.
- Lotrel (+18% US), the No. 1 US fixed combination treatment for hypertension, delivered doubledigit net sales growth in 2004, amid an increased focus on the efficacy of antihypertension agents in the US. Lotrel has expanded its position as the No. 1 branded combination therapy, a position held since 2002, based on greater awareness of the need for patients to achieve lower blood pressure goals set by national guidelines. Lotrel, which is sold only in the US, also benefited from the US hypertension awareness program.

- Lamisil (+19%; +14% lc; +23% US), the leading treatment wordwide for fungal nail infections, achieved net sales of more than \$1 billion for the first time after extending its US market segment leadership position to a high of 72% (IMS Health data as of November 2004). Higher disease awareness in the US and in leading European markets were key growth drivers, with France reporting the highest net sales in Europe.
- *Elidel* (+49%; +47% lc; +36% US), the world's No. 1 branded prescription agent for eczema, outperformed the market segment growth (+54% *Elidel* vs. 7.8% IMS top 16 countries as of October 2004) to deliver excellent net sales. In 2004, the influential UK National Institute for Clinical Excellence (NICE) recommended the use of *Elidel*, which is now available in approximately 90 countries worldwide, for treating appropriate cases of eczema.
- Zelnorm/Zelmac (+81%; +80% lc +89% US), a breakthrough therapy for irritable bowel syndrome (IBS) with constipation (IBS-C) and the first and only prescription medicine for chronic idiopathic constipation, reached \$299 million in net sales. A key driver has been increasing patient and physician awareness of the availability of a medicine to treat these diseases effectively. Results of the ZENSAA study published in 2004 showed the treatment to be highly effective as a repeat treatment for women with IBS and additionally demonstrated dramatic improvements in important quality of life measures. This study was the basis for resubmission in the European Union in October 2004, with a decision expected in 2005. The US Food and Drug Administration (FDA) granted approval in August 2004 for the additional indication of treating chronic idiopathic constipation in both men and women under age 65.

# Specialty Medicines

## Oncology

Net sales rose 28% to \$4.2 billion driven by growth in the following products:

- *Gleevec/Glivec* (+45%; +36% lc; +23% US), for all stages of Philadelphia-chromosome positive (Ph+) chronic myeloid leukemia (CML) and certain forms of gastro-intestinal stromal tumors (GIST), continued to grow dynamically amid further penetration of both the CML and GIST markets as well as continued increases in the average daily dose. New data presented at the American Society of Hematology meeting in December demonstrated that most newly diagnosed patients with Ph+ CML receiving 400 mg daily maintained their response to therapy long term. A separate study found patients receiving 800 mg daily had better outcomes compared to patients receiving 400 mg daily. In addition, encouraging data on the use of *Gleevec/Glivec* in the treatment of Ph+ acute lymphoblastic leukemia (ALL) and gliobastoma multiforme (GBM) were presented at major medical meetings in the fourth quarter. The *Glivec* International Patient Assistance Program is now open in 71 countries, and the combined *Gleevec/Glivec* patient assistance programs are providing treatments to more than 10,000 patients worldwide who otherwise would not have access to this innovative therapy.
- Zometa (+21%; +17% lc; US: +10%), the top intravenous bisphosphonate for bone metastases, achieved blockbuster status in 2004 by continuing to post solid growth despite challenges related to US Medicare reimbursement policy and increasing competition as well as high penetration rates in breast cancer and myeloma. *Zometa* continued to make progress on increasing the use of intravenous (IV) bisphosphonates in the treatment of prostate and lung cancer patients, two of the most common forms of cancer worldwide.
- *Femara* (+70%; +62% lc; US: +137%), a leading first-line therapy for early and advanced breast cancer in postmenopausal women, generated high double-digit growth in 2004. *Femara* has now been approved in 20 countries, including the US, for a new indication as the only post-tamoxifen treatment for early breast cancer based on the landmark MA-17 study, which showed *Femara* significantly increased a woman's chance of staying cancer-free following five years of adjuvant (post-surgery) tamoxifen therapy.

## **Ophthalmics**

Net sales rose 25% (+19% lc) to \$0.8 billion based on a continued strong performance from Visudyne (+25%; +20% lc; +15% US), the world's leading treatment for "wet" AMD (age-related macular degeneration), the leading cause of blindness in people over age 50 in developed countries. Improved US Medicare reimbursement for additional lesion types supported US sales growth, while sales in Europe remained strong.

## Transplantation

Net sales rose 1% (-5% lc) to \$1.1 billion as the *Neoral/Sandimmun* franchise (-1%; -7% lc; -17% US) experienced slightly decreased net sales worldwide although, market share gains were made in the US liver transplant segment because of an overall slow erosion by generic competition in the US and some other key markets. *Myfortic*, an immunosuppressant used in kidney transplant patients, was launched in over 40 countries, including the US, and continued to gain market share. *Certican*, a novel proliferation signal inhibitor, received European Union Mutual Recognition Procedure review from 10 new EU accession countries and was approved in Australia. We celebrated our 20 years of experience in transplantation in 2004 at the International Society of Transplantation meeting in Vienna.

Brands	Therapeutic Area	United States	% change in local currencies	Rest of the World	% change in local currencies	Total	% change in local currencies
		(\$ millions)		(\$ millions)		(\$ millions)	
Diovan/Co-Diovan	Hypertension	1,323	20	1,770	25	3,093	22
Gleevec/Glivec	Chronic myeloid leukemia/Gastro-						
	intestinal stromal						
	tumors	368	23	1,266	41	1,634	36
Lamisil (group)	Fungal infections	528	23	634	7	1,162	14
Zometa	Cancer						
	complications	630	10	448	29	1,078	17
Neoral/Sandimmun .	Transplantation	180	(17)	831	(4)	1,011	(7)
<i>Lotrel</i>	Hypertension	920	18			920	18
Sandostatin (group) .	Acromegaly	374	18	453	11	827	14
Lescol	Cholesterol						
	reduction	284	(8)	474	3	758	(2)
Voltaren (group)	Inflammation/pain	9	13	629	1	638	1
Trileptal	Epilepsy	391	28	127	30	518	29
Top ten products		5,007	15	6,632	16	11,639	16
Visudyne	Wet form of age- related macular						
	degeneration	209	15	239	25	448	20
Exelon	Alzheimer's disease	179	(1)	243	20	422	10
CR/XR)	Epilepsy	103	(16)	293	5	396	(2)
<i>Femara</i>	Breast cancer	166	137	220	29	386	62
Miacalcic	Osteoporosis	236	(1)	141	(13)	377	(6)
Elidel	Eczema	279	36	70	123	349	47
Foradil	Asthma	13	44	308	1	321	2
Leponex/Clozaril	Schizophrenia	72	(16)	236	(3)	308	(7)
Zelnorm/Zelmac	Irritable bowel		~ /		~ /		~ /
	syndrome	249	89	50	45	299	80
Famvir	Viral infections	160	10	95		255	6
Top twenty products .		6,673	17	8,527	15	15,200	16
Rest of portfolio		695	(20)	2,602	(5)	3,297	(9)
Total		7,368	12	11,129	9	18,497	10

# Top 20 Pharmaceutical Division Product Net Sales-2004

## **Consumer Health Division**

Net sales rose 10% (+5% lc) to \$9.8 billion as double-digit net sales expansion, in part due to currency exchange benefits resulting from a weakness of the US dollar, in OTC, Animal Health and Medical Nutrition offset slower growth in Sandoz, Infant & Baby and CIBA Vision. Volume expansion overall in Consumer Health contributed two percentage points to growth, while currencies added five percentage points. Price increases, on average, were insignificant.

# Sandoz

Sandoz net sales rose 5% (-1% lc) to \$3.0 billion following an exceptionally strong 2003 performance driven by the launch of the antibiotic AmoxC in the US. Competitive pricing pressures also emerged during 2004 especially in the US and Germany.

## OTC (Over-The-Counter self-medications)

OTC net sales climbed 11% (+5% lc) to \$2.0 billion, led by strong performances from key strategic brands, including the smoking cessation product *Nicotinell/Habitrol*, the topical OTC version of the antifungal agent *Lamisil* and the laxatives *Ex-Lax/Benefiber*. Another key growth driver was the introduction of a new thin-film form of the cold/cough remedies *Triaminic/Thera-Flu*, strategic OTC brands, that melts on the tongue with no need for water.

## Animal Health

Animal Health net sales reported a 11% (+5% lc) increase to \$0.8 billion, supported by double-digit growth in the companion-animal franchise and strong market share gains for new brands such as *Deramaxx* for the treatment of pain and inflammation associated with osteoarthritis in dogs as well as *Milbemax* for intestinal worm control in dogs and cats. Growth from these new products helped to offset the loss of net sales from recently divested products. In the farm animal franchise, the farm fly control product *Agita* supported net sales growth.

## Medical Nutrition

Medical Nutrition net sales rose 38% (+31% lc) to \$1.1 billion, due mainly to the successful completion in February 2004 of the acquisition of the adult medical nutrition business of Mead Johnson from Bristol-Myers Squibb Company. This acquisition added 28 percentage points to Medical Nutrition's net sales growth in 2004. Organic growth was driven by a continued focus on targeting the needs of patients with specific diseases such as cancer and diabetes and on the home-care channel.

## Infant & Baby

Infant & Baby net sales grew 6% (+6% lc) to \$1.4. billion, outpacing industry growth due to the Gerber baby food brand in the US. The packaging conversion to plastic jars continued to boost net sales in the US baby food segment, as did the launch of innovative finger food products for toddlers.

## CIBA Vision

CIBA Vision net sales were up 8% (+2% lc) to \$1.4 billion, supported by ongoing growth of the *DAILIES, NIGHT & DAY* lenses and the lens care product range. CIBA Vision launched its  $0_2$  *Optix* product range in 2004, a group of contact lenses with higher oxygen transmissibility, to competitively penetrate the weekly/monthly lens segment.

#### 3. Operating Expenses

	Year ended E			
	2004	2003	Change in \$	
	(\$ millions)	(\$ millions)	(%)	
Net sales	28,247	24,864	14	
Cost of Goods Sold	(6,625)	(5,894)	12	
Marketing & Sales	(8,873)	(7,854)	13	
Research & Development	(4,207)	(3,756)	12	
General & Administration	(1,540)	(1,381)	12	
Other Income & Expense	(463)	(90)		
Operating income	6,539	5,889	11	

#### Cost of Goods Sold

Cost of Goods Sold rose 12% to \$6.6 billion in 2004 but fell as a percentage of net sales to 23.5% in 2004 from 23.7% in 2003 due mainly to ongoing productivity improvements and a favorable product mix in Pharmaceuticals.

Our current definition of Cost of Goods Sold excludes the amortization and impairment of product and patent rights and trademarks. \$264 million amortization and impairment charges (2003: \$260 million) relating to these intangibles are included in Other Operating Expenses. Had these charges been included in Cost of Goods Sold then the gross profit margin would have been 75.6% and 75.2% in 2004 and 2003, respectively.

## Marketing & Sales

Marketing & Sales expenses increased 13% to \$8.9 billion but declined slightly as a percentage of net sales to 31.4% compared to 31.6% in 2003, mainly reflecting the impact of productivity gains in the Pharmaceuticals US sales-force.

#### **Research & Development**

Research & Development expenses rose 12% in 2004 to \$4.2 billion, reflecting investments in the Novartis Institutes for BioMedical Research in the US, but declined as a percentage of net sales to 14.9% compared to 15.1% in 2003, partly reflecting lower development milestone payments compared to 2003.

## **General & Administration**

General & Administration expenses rose 12% to \$1.5 billion in 2004 expanding at a slower pace than net sales, leading to a modest improvement as a percentage of net sales to 5.5% compared to 5.6% in 2003.

# **Other Income & Expense**

Other Income & Expense was a net charge of \$463 million in 2004 compared to \$90 million in 2003, reflecting a series of factors that included \$102 million less Corporate pension income, \$171 million less hedging gains on intragroup sales, as well as lower income from product divestments principally related to the \$178 million gain in 2003 from selling the *Fioricet/Fiorinal* product range and \$37 million additional impairment and restructuring charges in Sandoz.

As noted above Other Income & Expense includes \$264 million (2003: \$260 million) of amortization and impairment charges related to product and patent rights and trademarks. Under US GAAP, these expenses would be included in Cost of Goods Sold.

#### 4. Operating Income by Division and Business Unit

Operating income growth advanced 11% to \$6.5 billion at a slower rate than net sales due to higher Other Operating Expenses in 2004 leading to an operating margin decline of 0.6 percentage points from 23.7% of net sales in 2003 to 23.1% in 2004.

	Year ended l			
	2004	2003	Change in \$	
	(\$ millions)	(\$ millions)	(%)	
Pharmaceuticals	5,253	4,423	19	
Sandoz	235	473	(50)	
OTC	351	309	14	
Animal Health	78	88	(11)	
Medical Nutrition	32	82	(61)	
Infant & Baby	274	254	8	
CIBA Vision	236	153	54	
Divisional Management	(25)	(39)	(36)	
Consumer Health	1,181	1,320	(11)	
Corporate income, net	105	146	(28)	
Total	6,539	5,889		

#### Pharmaceuticals Division

In Pharmaceuticals, operating income expanded significantly faster than net sales, rising 19% to \$5.3 billion. This resulted in a margin expansion of 0.8 percentage points to 28.4% of net sales from 27.6% in 2003. An improvement of 0.8 percentage points in Cost of Goods Sold (COGS), mainly from productivity gains and improved product mix, was an important contributor. Marketing & Sales expenses fell 0.2 percentage points to 33.0% based in part on sales-force productivity improvements, particularly in the US. Research & Development expenses rose 13% on investments in the Novartis Institutes for BioMedical Research (NIBR) and late-stage clinical trial programs. However, R&D expenses declined 0.4 percentage points to 18.8% as fewer upfront development costs were paid compared to 2003. Other Operating Expenses increased 56% as a result of several factors, including a decline of \$171 million in hedging gains on intragroup sales and lower income from product divestments compared to 2003, which included a one-time gain of \$178 million from the sale of the *Fioricet/Fiorinal* product range. General & Administrative costs fell to 3.5% of net sales from 3.6% in 2003.

# **Consumer Health Division**

Operating income declined 11% to \$1.2 billion despite strong expansion in OTC, Animal Health and CIBA Vision. One-off charges of \$120 million were recorded, which included \$37 million in restructuring charges and related impairments of property, plant & equipment at Sandoz, a one-time inventory write-down of \$18 million in Animal Health, one-time costs of \$14 million associated with the acquisition of Mead Johnson and the creation of a \$51 million provision in Medical Nutrition to cover legal liabilities related to an investigation by the US Department of Justice in the US enteral pump market. Novartis Nutrition Corporation is currently in the process of negotiating a possible settlement of that portion of the investigation directed against it which is described in more detail in Item 8.A.7—legal proceedings. Excluding these one-off items, operating income would have declined 1% to \$1.3 billion and the operating margin would have been 13.3% compared to 14.9% in 2003.

#### Sandoz

Operating income declined sharply to \$235 million compared to \$473 million in 2003, due primarily to the impact of competitive pressures on pricing, particularly in the US and Germany. As a consequence, a further impairment of our German operation's goodwill of \$73 million was required due to the effects that competitive pressures were likely to have on the business outlook. This follows a similar impairment of \$72 million recorded in 2003. Other operating expenses also included \$37 million of restructuring charges and related impairments of property, plant & equipment related to operations in Germany, Italy, Austria and Slovenia affecting 363 employees in total. The operating margin fell to 7.7% compared to 16.3% in 2003.

# OTC (over-the-counter self medication)

Operating income rose 14% to \$351 million, benefiting from strong volume growth in strategic brands and tight cost control as well as the 2003 impact of non-recurring costs from exiting a Japanese joint venture.

#### Animal Health

Operating income fell 11% to \$78 million, due mainly to the negative impact of a one-time inventory write-down of \$18 million.

### Medical Nutrition

Despite productivity gains and product mix improvements, operating income fell 61% to \$32 million. The decline was due principally to the recording of a provision of \$51 million with regard to an investigation by the US Department of Justice in the US enteral pump market, including whether certain US federal criminal statutes have been violated. Novartis Nutrition Corporation is currently in the process of negotiating a possible settlement of that portion of the investigation directed against it which is described in more detail in Item 8.A.7—legal proceedings. In addition, one-time expenses of \$14 million were associated with the Mead Johnson acquisition. Excluding these one-off charges operating income would have increased 18.3% to \$97 million and the operating margin would have been 8.7% compared to 10.1% in 2003.

# Infant & Baby

Operating income rose 8% to \$274 million as the operating margin improved to 19.0% from 18.7% in 2003.

# CIBA Vision

Operating income reached \$236 million, an increase of 54% over 2003, due mainly to the divestment of loss making activities in late 2003 and improved net sales volumes and product mix. The operating margin increased to 16.7% in 2004 compared to 11.7% in 2003.

#### Corporate Income, net

Net Corporate income totaled \$105 million in 2004, compared to \$146 million in 2003. The principal reason for the fall was \$102 million less pension income in 2004 compared to 2003.

### 5. Net income

The following table sets forth selected income statement data for the periods indicated.

	Year ended <b>E</b>	December 31,	
	2004	2003	Change in \$
	(\$ millions)	(\$ millions)	(%)
Operating income	6,539	5,889	11
Results from associated companies	142	(200)	
Financial income, net	227	379	(40)
Income before taxes and minority			
interests	6,908	6,068	14
Taxes	(1,126)	(1,008)	12
Income before minority interests	5,782	5,060	14
Minority interests	(15)	(44)	(66)
Net income	5,767	5,016	15

#### **Results from associated companies**

Associated companies are accounted for using the equity method when we own between 20% and 50% of the voting shares of these companies. Income from associated companies is mainly derived from our investments in Roche Holding AG and Chiron Corporation. Overall, income from associated companies increased to \$142 million from an expense of \$200 million in 2003.

Our 42.5% interest in Chiron contributed pre-tax income of \$33 million compared to \$134 million in 2003. This reduction was mainly due to manufacturing production issues at a Chiron site in the United Kingdom that prevented Chiron from delivering flu vaccines to the US for the 2004/2005 flu season.

Our 33.3% interest in Roche voting shares, which represents a 6.3% interest in the total equity of Roche, generated pre-tax income of \$97 million compared to a pre-tax loss of \$354 million in 2003. The 2003 performance was due to Roche's unexpected loss of CHF 4.0 billion in 2002 which was reflected by us as a change in estimate in 2003. The pre-tax income for 2004 reflects an estimate of our share of Roche's 2004 pre-tax income, which is \$399 million, including a positive prior year adjustment of \$30 million. This income was reduced by a goodwill and intangible amortization charge of \$302 million arising from the allocation of the purchase price to property, plant & equipment and intangible assets and goodwill.

A survey of analyst estimates is used to predict our share of the net income of both Roche and Chiron. Any differences between these estimates and actual results will be adjusted in 2005.

## Financial income, net

Because of the ongoing low-yield environment, net financial income was \$227 million in 2004 compared to \$379 million in 2003. The overall return on net liquidity was 3.4%, compared to 5.2% in the year-ago period. See Item 11 for a discussion of our risk management policy, the employment of financial instruments and their accounting.

The following table provides an analysis of our sources of net financial income:

	Equity options (\$ millions)	Bond options (\$ millions)	Forward exchange contracts (\$ millions)	Foreign exchange options (\$ millions)	Interest Rate Swaps/Cross Currency Swaps/ Forward Rate Agreements (\$ millions)	Total (\$ millions)
2004	(\$ 111110115)	(\$ 111110115)	(\$ 111110115)	(@	(@ 111110115)	(@ 111110115)
Income on options and forward contracts	93	9	59	68	77	306
Expenses on options and forward contracts	(104)	(8)	(162)	(58)		(332)
<b>Options and forward contracts</b>						
results, net	(11)	1	(103)	10	77	(26)
Net interest          Dividend income          Net capital gains          Impairment of marketable						127 12 123
securities Other financial result, net Currency result, net						(66) (39) <u>96</u>
Total financial income, net						227
2003						
Income on options and forward contracts Expenses on options and	270		185	331	327	1,113
forward contracts	(419)		(140)	(250)		(809)
<b>Options and forward contracts</b>						
results, net	<u>(149</u> )		45	81	327	304
Net interest Dividend income Net capital gains Impairment of marketable						80 17 11
securities Other financial result, net						(66) (31)
Currency result, net						<u>64</u> <u>379</u>

### Taxes

The tax charge of \$1.1 billion increased by 12% compared to 2003. Our effective tax rate (taxes as a percentage of income before tax) was 16.3% in 2004 compared to 16.6% in 2003.

Our expected tax rate (weighted average tax rate based on the result before tax of each subsidiary) was 16.8% in 2004 compared to 14.8% in 2003. Our effective tax rate is different than the expected tax rate due to the effect of equity accounting in the income statement for associated companies of 0.7 percentage points (2003: 1.9 percentage points) and various adjustments to expenditures and income

for tax purposes. See note 6 to the consolidated financial statements for details of the main elements contributing to the difference.

# Net income

Net income grew 15% to \$5.8 billion from \$5.0 billion in 2003. As a percentage of total net sales, net income rose to 20.4% in 2004 compared to 20.2% in 2003 due mainly to the strong improvement in operating income.

Return on average equity was 18.0% in 2004 (17.1% in 2003).

## 2003 Compared to 2002

The following compares our results in the year ended December 31, 2003 to those of the year ended December 31, 2002. Our analysis is divided as follows:

- 1. Overview
- 2. Net Sales by Division and Business Unit
- 3. Operating Expenses
- 4. Operating Income by Division and Business Unit
- 5. Net Income

# 1. Overview

In US dollars, our net sales in 2003 increased by 19% over 2002 to \$24.9 billion (+11% in local currencies); operating income grew by 16% to \$5.9 billion; net income increased by 6% to \$5.0 billion; and cash flow from operating activities increased by 27% to \$6.7 billion.

Our Pharmaceuticals Division accounted for 64% of our total net sales and our Consumer Health Division accounted for 36%. The two Divisions generated 77% and 23% of divisional operating income, respectively.

Geographically, 45% of our net sales were generated in the North American Free Trade Association (NAFTA) region (41% in the USA), 35% in Europe and 20% in the rest of the world.

Net sales growth was driven by a volume increase of 8%. All Business Units except Sandoz and CIBA Vision benefited from small price increases which in total amounted to 1%. The net sales increase due to acquisitions was 2%. The sales performance in US dollars benefitted from a 8% positive currency effect as the US dollar weakened on average 16% against the Swiss franc, 8% against the yen and 20% against the euro.

Our operating margin in 2003 was 23.7% of net sales, a decrease of 0.7 percentage points over the 24.4% of net sales of the previous year. As a percentage of net sales, productivity gains and improvements in the product mix led to a 0.2 percentage point reduction in the Cost of Goods Sold, while Marketing & Sales expenses decreased by 0.7 percentage points, although still increasing by 17% over 2002, to support product launches and key growth drivers. Research & Development investments were increased by 32% mainly due to increased development expenses, especially connected with milestone payments on in-licensed compounds, and due to the Pharmaceuticals Division research strategy of establishing a new facility in Cambridge, US. General & Administration expenses grew by 21%, 2% more than net sales.

As a result of all these factors, operating income increased 16% in US dollars to \$5.9 billion.

# 2. Net Sales by Division and Business Unit

The following table sets forth selected sales data for each of the periods indicated.

	Year ended l	December 31,		Change in local
	2003	2002	Change in \$	currencies
	(\$ millions)	(\$ millions)	(%)	(%)
Sales				
Pharmaceuticals	16,020	13,528	18	11
Sandoz	2,906	1,817	60	47
OTC	1,772	1,521	17	7
Animal Health	682	623	9	3
Medical Nutrition	815	711	15	3
Infant & Baby	1,361	1,333	2	3
CIBA Vision	1,308	1,135	15	7
Consumer Health—ongoing	8,844	7,140	24	16
Divested Health & Functional Food				
activities		209		
Consumer Health	8,844	7,349	20	12
Total	24,864	20,877	19	11

As discussed in the Critical Accounting Policies Section, the US market has the most complex arrangements in the area of deductions from gross sales to arrive at net sales, which is the starting point for all our discussions on our sales developments. The following table shows the extent of rebates made in the US for our key subsidiaries affected, which are Novartis Pharmaceuticals Corporation, Sandoz Inc. and Novartis Consumer Health Inc. (OTC):

# Gross to Net sales reconciliation in the US

	2003	% of gross sales	2002	% of gross sales
Gross Sales subject to deductions	(\$ millions) 10,429	100	(\$ millions) 9,215	100
Medicaid & Medicare rebates and prescription				
drug saving cards	(390)	(4)	(270)	(3)
Managed Health Care rebates & other rebates	(557)	(5)	(493)	(5)
Chargebacks including Hospital chargebacks	(1,008)	(10)	(1,045)	(11)
Sales Returns	(184)	(2)	(193)	(2)
Other deductions	(411)	(4)	(350)	(4)
Total Gross to Net sales adjustments $^{(1)}$	(2,550)	(25)	(2,351)	(25)
Net sales	7,879	75	6,864	75

<sup>(1)</sup> \$38 million was charged directly to the Income Statement without being recorded in the Revenue Deduction Accruals (2002: \$37 millions).

No major changes occurred in the above percentage deductions from gross sales between 2003 and 2002.

#### Pharmaceuticals Division

Our core Pharmaceuticals business sustained above market net sales growth throughout the year to deliver an 18% rise in net sales (11% in local currencies). We moved up to the number five position in the global health care ranking (based on November 2003 IMS data) as we captured further segment share in the key US market (net sales: +15% in US dollars), in Japan (net sales: +23%; +14% in local currencies), the second largest single market, as well as in Europe (net sales: +25%; +6% in local currencies). Based on latest available data (IMS), our overall share of the global health care market rose to 4.4% in 2003.

Our cardiovascular (+36%; +29%) in local currencies) and oncology franchises (+36%; +26%) in local currencies) continued to be the main drivers, led in particular by the flagship brands *Diovan*, *Lotrel*, *Lescol*, *Glevec/Glivec*, *Zometa* and *Femara*.

Newly launched products made further in-roads; *Zelnorm/Zelmac* generated net revenues of \$165 million, with US total and new prescriptions growing 32% in the fourth quarter. Meanwhile, net sales of *Elidel* reached \$235 million, as the product extended its position as the number-one branded eczema treatment worldwide.

# Primary Care

• *Diovan* (+46%; +38% in local currencies; US: +42%) became in 2003 the world's leading angiotensin receptor blocker (ARB) and continued to capture further market share from its competitors. With the heart failure indication approved in more than 40 markets, the flagship brand continued to outpace its fast-growing ARB market segment, with year-to-date net sales in the US surpassing the \$1 billion mark by December.

The fourth quarter was marked by the publication of the VALIANT mega-trial at the American Heart Association Scientific Session. The results showed that *Diovan* reduces the risk of death by 25% in post-myocardial infarction patients. A supplemental new drug application based on these results was filed in the US.

- *Diovan HCT* (valsartan + hydrochorothiazide) became the second most prescribed product in the combination ARB segment (mono and combination therapy) in the US. This rapid growth was powered by the roll-out of new dosage forms, the heart failure indication and new treatment guidelines. In Germany, the flagship brand secured the number-one rank, buoyed by the success of *Co-Diovan* 160/12.5 mg.
- Lotrel (US: +20%), the leading combination treatment for hypertension, posted strong full-year
  prescription growth while fourth-quarter net sales were spurred by a disease awareness campaign
  launched in August. Overall, the brand steadily gained market segment share as a result of Joint
  National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
  (JNC7) guidelines recommending more aggressive treatment; a focus on patients who are not
  controlled by ACE inhibitors and calcium channel blockers; and the successful launch of the new
  dosage strength, which add efficacy and dosing flexibility.
- Lescol (+27%; +18% in local currencies; US: +19%; cholesterol reduction) continued strong net sales growth driven by proven benefits in high-risk patients, the successful rollout of the XL (extended release) formulation in France, Italy and Spain and the launch of the secondary prevention indication in the US.
- *Trileptal* (+42%; +39% in local currencies; US: +43%; epilepsy) clearly outpaced its market. In August, the FDA granted approval for the use of *Trileptal* as monotherapy in children. *Trileptal* was now indicated for the treatment of partial seizures as a monotherapy and adjunctive therapy in adults and children of 4 years and upwards.

- *Elidel* (+147%; +144% in local currencies; US: +125%; non-steroid eczema treatment) achieved full year net sales of \$235 million, generated predominantly in the US. In less than two years since its first launch, *Elidel* became the number-one branded prescription treatment for eczema and was available in more than 38 markets.
- Zelnorm/Zelmac (irritable bowel syndrome with constipation) net revenues reached \$165 million (US: \$132 million) reflecting the product's therapeutic benefits and the increase in disease awareness. Total US prescriptions as well as new prescriptions recently increased more than 32%. Zelnorm/Zelmac was launched in 39 countries and was filed, in the fourth quarter, for the new indication of chronic constipation in the US.

# Oncology

Net sales rose 36% to \$3.3 billion driven by growth in the following products:

- *Gleevec/Glivec* (+84%; +68% in local currencies; US: +41%), for chronic myeloid leukemia (CML) and gastro-intestinal stromal tumors (GIST), continued to grow dynamically, boosted by its use as first-line therapy and its approval for GIST in the US, Europe and Japan. The number of patients enrolled in the *Gleevec/Glivec* Patient Assistance Program rose to more than 8,000 worldwide, providing treatment to many needy patients who otherwise would not have access.
- Zometa (+83%; +74% in local currencies; US: +59%), the most prescribed intravenous bisphosphonate for bone metastases, continued to post dynamic growth. Several launches in Europe fueled additional growth, as did the continued expanded use into a number of tumor types including lung, prostate, multiple myeloma, and breast.
- Sandostatin (+14%; +7% in local currencies; US: +13%; acromegaly and carcinoid syndrome) net sales continued to grow, driven by US net sales.
- *Femara* (first-line therapy for advanced breast cancer in postmenopausal women) achieved a 30% rise (+18% in local currencies; US: + 22%) in net sales supported by its strong profile and the landmark results of the MA-17 study published in the fourth quarter. These showed a 43% reduction in the risk of cancer recurrence, in addition to significantly improved disease-free survival in postmenopausal women with early breast cancer, who had completed five years of tamoxifen therapy.

# **Ophthalmics**

Net sales rose 9% to \$0.6 billion driven by growth of Visudyne.

• *Visudyne* (+24%; +16% in local currencies; US: +8%; treatment in age-related macular degeneration) continued to post overall growth, benefiting from increased market penetration and strong net sales in Europe, Latin America and the Asia Pacific regions.

# Transplantation

Net sales decreased slightly by 1.9% to \$1.1 billion.

- *Neoral/Sandimmun* (immunosuppression) net sales declined only modestly (-10% in local currencies) despite the use of lower dosing regimen in the US, in addition to generic competition and compulsory price-cuts in Germany and Italy. Sales momentum was sustained in Japan even though reimbursement was reduced by the authorities.
- *Myfortic*, the new enteric-coated formulation of mycophenolate sodium used to prevent organ rejection, gained approval in 27 countries by the end of 2003.

Brands	Therapeutic Area	United States	% change in local currencies	Rest of the World	% change in local currencies	Total	% change in local currencies
		(\$ millions)		(\$ millions)		(\$ millions)	
Diovan/Co-Diovan	Hypertension	1,107	42	1,318	34	2,425	38
Gleevec/Glivec	Chronic myeloid leukemia/ Gastro-intestinal stromal tumors	299	41	829	82	1,128	68
Neoral/Sandimmun	Transplantation	216	(21)	804	(6)	1,020	(10)
Lamisil (group)	Fungal infections	428	2	550	9	978	5
Zometa	Cancer complications	574	59	318	118	892	74
Lotrel	Hypertension	777	20			777	20
Lescol	Cholesterol reduction	309	19	425	18	734	18
Sandostatin (group)	Acromegaly	318	13	377	2	695	7
<i>Voltaren</i> (group) <i>Cibacen/Lotensin/</i>	Inflammation/pain	8	(33)	591	(5)	599	(6)
Cibadrex	Hypertension	306	(9)	127	(8)	433	(9)
Top ten products		4,342	21	5,339	20	9,681	20
Trileptal	Epilepsy	305	43	92	27	397	39
<i>Miacalcic</i>	Osteoporosis	239		150	(14)	389	(6)
Tegretol (incl. CR/XR) .	Epilepsy	122	1	262	(1)	384	
<i>Exelon</i>	Alzheimer's disease	181	8	186	19	367	13
Visudyne	Wet form of age-related macular degeneration	181	8	176	27	357	16
Leponex/Clozaril	Schizophrenia	86	(28)	223	(2)	309	(12)
Foradil	Asthma	9	(61)	280	2	289	(4)
<i>Elidel</i>	Eczema	205	125	30	575	235	144
Famvir	Viral infections	146	(7)	87	19	233	
HRT Range	Hormone replacement	125	(9)	106	(24)	231	(16)
Top twenty products		5,941	18	6,931	16	12,872	17
Rest of portfolio		643	(9)	2,505	(9)	3,148	(9)
Total		6,584	15	9,436	8	16,020	11

# Top 20 Pharmaceuticals Division Product Net Sales-2003

#### **Consumer Health Division**

Net sales in our Consumer Health Division's ongoing businesses grew a substantial 24% (+16% in local currencies) driven mainly by the Sandoz generics Business Unit, and fueled by above-market net sales growth throughout the other businesses, of which OTC, Medical Nutrition and CIBA Vision all delivered double-digit net sales increases in US dollars.

# Sandoz

Net sales at Sandoz rose 60% (+47% in local currencies) to \$2.9 billion, driven by the US Generic Pharmaceuticals Business and the Lek acquisition, which contributed 38 percentage points to net sales growth. The US net sales increased by 56% fuelled by the strong sales of AmoxC (the generic version of Augmentin<sup>®</sup>) and by the successful roll-out of prescription loratadine (a generic version of the allergy treatment Claritin<sup>®</sup>). Further impetus was added through the roll-out of citalopram in the UK (a generic version of the anti-depressant Celexa<sup>®</sup>) and of omeprazole in the US (a generic version of the ulcer and heartburn treatment Prilosec<sup>®</sup>).

The Industrial Business posted a net sales increase of 12% in US dollars and a 6% decrease in local currencies. Sandoz also continued its efforts to develop its new Biopharmaceuticals Business, focused on the manufacture of active ingredients, mostly modern recombinant products.

# OTC (over-the-counter self medication)

In 2003, OTC net sales rose 17% (7% in local currencies) to \$1.8 billion, led by *Nicotinell/Habitrol* (smoking cessation), *Lamisil* (topical antifungal), and by *Ex-Lax/Benefiber* (laxative) with US private-label loratadine also contributing to overall net sales growth.

# Animal Health

Net sales were up 9% in US dollars or 3% in local currencies to \$682 million.

Net sales at the companion animal franchise grew in double-digits, driven in particular by strong market share gains of the new brands *Deramaxx* (pain and inflammation control associated with osteoarthritis in dogs) and *Milbemax* (intestinal worm control in dogs and cats). *Fortekor* (heart/kidney disease), strengthened by a novel palatable formulation for cats, complemented results again with a net sales increase well above market growth.

In the farm-animal franchise *Agita*, the innovative farm fly control product consistently added to net sales, while the therapeutic anti-infectives business contended with increased generic competition especially in the pig market.

# Medical Nutrition

Net Sales reached \$815 million, up 15% in US dollars (+3% in local currencies).

Double digit growth in Europe lifted Medical Nutrition net sales, which were driven by the strong performance of Enteral Nutrition (*Isosource* and *Novasource*) and additional net sales impetus from the Medical Food franchise (*Resource*). In Nutrition & Santé, net sales growth from the core brands offset the impact of distributor changes in China and Italy, while Sports Nutrition net sales were lifted by the introduction of *Isostar "Fast Hydration"*.

### Infant & Baby

Net sales grew 2% (3% in local currencies) outpacing industry growth and leading to overall net sales of \$1.4 billion. The major contributor was *Gerber* in the US, spurred by innovations in the Juice, Graduates, and *Tender Harvest* lines and the success of the *Lil' Entrees* line of microwavable convenience trays targeted at the toddler segment.

# CIBA Vision

Net sales grew 15% in US dollars terms and rose 7% in local currencies to \$1.3 billion, driven by the growth of *Focus DAILIES* and *Focus NIGHT & DAY* lenses which allowed the company to maintain leadership of the daily disposables and continuous wear categories. *Focus DAILIES Toric*, the world's first and only daily disposable lens for astigmatism correction, was launched also in the US and Japan following last year's introduction in Europe. *FreshLook* colored lenses remained the leading brand in the cosmetic lens segment, supported by the launch of *FreshLook Radiance* and *FreshLook Dimensions*. More emphasis was put on direct-to-consumer advertising with new successful TV and print campaigns for *Focus NIGHT & DAY* and *FreshLook*.

Despite competing in a shrinking market, net sales of lens care products were flat versus the prior year, supported by the launch of *AOSEPT ClearCare* in US and *SOLO-Care AQUA* in selective European countries. Sales of *FreshLook Care* in Japan continued to grow.

The ophthalmic surgical business contributed growing net sales during the year. In August 2003, CIBA Vision announced its intention to pursue strategic alternatives for this business, including its potential sale. Agreements were reached with certain third parties to sell to them certain assets of the surgical business.

### 3. Operating Expenses

The following table sets forth our operating expenses.

	Year ended I	December 31,	
	2003	2002	Change in \$
	(\$ millions)	(\$ millions)	(%)
Net Sales	24,864	20,877	19
Cost of Goods Sold	(5,894)	(4,994)	18
Marketing & Sales	(7,854)	(6,737)	17
Research & Development	(3,756)	(2,843)	32
General & Administration	(1,381)	(1,146)	21
Other Income & Expense	(90)	(65)	39
Operating income	5,889	5,092	16

#### Cost of Goods Sold

Cost of Goods Sold decreased as a percentage of net sales from 23.9% in 2002 to 23.7% in 2003. This was mainly due to continued improvements in productivity and a favorable product mix in our Pharmaceuticals Division.

Our current definition of Cost of Goods Sold excludes the amortization and impairment of product and patent rights and trademarks. \$260 million amortization and impairment charges (2002: \$267 million) relating to these intangibles are included in Other Operating Expenses. Had these charges been included in Cost of Goods Sold then the gross profit margin would have been 75.2% and 74.8% in 2003 and 2002 respectively.

# Marketing & Sales

Marketing & Sales expenses as a percentage of net sales decreased by 0.7% over 2002 to 31.6% of net sales.

# **Research & Development**

Research & Development expenses increased 32% owing to in-licensing deals in our Pharmaceuticals Division and the build-up of the Cambridge research facility. As a percentage of net sales, Research & Development was 15.1% (2002: 13.6%).

# General & Administration

General & Administration expenses increased to 5.6% of net sales in 2003 from 5.5% in 2002 reflecting a modest increase.

### **Other Income & Expense**

Other Income & Expense was a net charge of \$90 million in 2003 compared to \$65 million in 2002, reflecting a series of factors including the impairment of property, plant and equipment and intangible assets of \$136 million and write-down of certain financial investments, including biotechnology ventures due to their poor performance, of \$80 million, exchange rate movements and royalty payments. Conversely this net charge was reduced by the release of \$90 million of legal provisions (at Corporate and Sandoz level) as a result of a litigation settlement with GlaxoSmithKline.

As noted above Other Income & Expense includes \$260 million (2002: \$267 million) of amortization and impairment charges related to product and patent rights and trademarks. Under US GAAP, these expenses would be included in Costs of Goods Sold.

# 4. Operating Income by Division and Business Unit

Operating income rose 16% to \$5.9 billion in 2003 compared to 2002 and the operating margin decreased 0.7 percentage points to 23.7% (2002: 24.4%). The following table sets forth selected operating income data for each of the periods indicated.

Year ended l		
2003	2002	Change in \$
(\$ millions) 4,423	(\$ millions) 3,891	(%) 14
473 309 88 82 254 153 (39)	265 240 92 4 227 118	78 29 (4) 12 30
1,320	<b>946</b> 140	40
<b>1,320</b> 146 <b>5,889</b>	<b>1,086</b> 115 <b>5,092</b>	22 27 16
	2003 (\$ millions) 4,423 473 309 88 82 254 153 (39) 1,320 1,320 146	$(\$ \text{ millions}) \\ \hline 4,423 \\ \hline 473 \\ \hline 265 \\ 309 \\ 240 \\ 88 \\ 92 \\ 82 \\ 4 \\ 254 \\ 254 \\ 254 \\ 227 \\ 153 \\ 118 \\ (39) \\ \hline 1,320 \\ \hline 946 \\ \hline 1,320 \\ \hline 1,086 \\ 146 \\ 115 \\ \hline \end{cases}$

# Pharmaceuticals Division

Earnings growth accelerated in the year as net sales continued to expand strongly. The Cost of Goods Sold, as well as investments in Marketing & Sales slightly decreased as a percentage of Division's net sales compared to the prior year, Research & Development increased significantly as considerable payments related to development milestones and attractive in-licensing deals were completed. Product-mix changes and productivity gains in the Cost of Goods Sold continued to drive gross profit improvements. Research & Development expenses reached 19.1% of Divisional net sales (reflecting the sustained high-level investment in the new Cambridge facilities and in-licensing opportunities). Other income & expense grew from 2.3% to 2.4% of Divisional net sales owing to several factors including the write-down of certain financial investments in biotechnology ventures due to their poor performance, exchange rate movements, royalty payments and increased product liability insurance costs. This was partially offset by one time gains on the sale of non-core products, primarily the *Fioricet* and *Fiorinal* lines for \$178 million. Gains on hedging intragroup sales recorded in the Division's other income & expenses were \$171 million in 2003 compared to \$176 million in 2002.

During 2003, our Pharmaceuticals Division completed a number of transactions to strengthen its product portfolio. In April, we acquired the urinary incontinence treatment *Enablex* (darifenacin) from Pfizer for a total of up to \$225 million, part of which was conditional on certain marketing approvals in the US and EU. In 2003, we also acquired the rights to the IL1-trap compound from Regeneron and the rights to develop and market Lucentis<sup>™</sup> outside North America from Genentech. These transactions resulted in

\$151 million of milestone payments. In May, we acquired an additional 51% of the capital stock of Idenix Pharmaceuticals Inc. of Cambridge, Massachusetts, for an initial payment of \$255 million.

# **Consumer Health Division**

Operating income from the ongoing business of our Consumer Health Division rose 40% in the year, outpacing net sales and driven in particular by Sandoz (+78%), where volume expansions and productivity gains, more than offset increased investments in Marketing & Sales and Research & Development. Apart from Sandoz, CIBA Vision (+30%), Medical Nutrition and OTC (+29%), all achieved considerable increases in operating income, the latter benefiting from the exceptional contribution of loratadine.

Overall, in Consumer Health continued productivity gains, lower costs of certain raw materials and product-mix improvements contributed to a reduction in the Cost of Goods Sold as a percentage of net sales. Marketing & Sales investments were maintained at a high level in order to drive recently launched products and to support key brands, however the increase was less than net sales growth. On the other hand, Research & Development investments increased overproportionally, which was mainly due to the expansion of internal Research & Development capabilities at Sandoz, licensing agreements and other initiatives to accelerate innovation.

Other income and expense increased mainly on account of the impairment of goodwill of \$72 million relating to Sandoz, Germany. The impairment of this goodwill was recorded after taking into account the entity's loss of market share, which in the near future, was considered to be difficult to regain. This was partially offset by the release of \$49 million of provisions following the successful conclusion of a litigation with GlaxoSmithKline.

With almost all Business Units achieving margin improvements, the Division's ongoing operating margin improved 1.7 percentage points to 14.9% of net sales.

# Sandoz

Operating income increased significantly by 78% over 2002, fueled by net sales growth especially related to the acquistion of Lek, productivity gains and a stronger focus on higher margin products and favorable product mix. This increase in operating income was achieved despite increases in Research & Development expenses. Research & Development investments increased 90% to \$263 million due to product developments and the funding of Research & Development in the US.

Other income and expense included a \$72 million goodwill impairment charge relating to the German activities however, benefited from a release of \$49 million of litigation provisions following the successful conclusion of negotiations with GlaxoSmithKline.

The operating margin rose 1.7 percentage points to 16.3%.

### OTC (over-the-counter self medication)

Operating income increased 29% over the year to \$309 million, as a result of net sales growth led by *Nicotinell/Habitrol* and the launch of private label loratadine in the US and the non-recurrence of exit costs from a Japanese joint venture. The operating margin increased 1.6 percentage points to 17.4%.

#### Animal Health

2003 operating income fell 4% to \$88 million, leading to an operating margin of 12.9% (2002: 14.8%). Operating costs increased due to Marketing & Sales investments focused on recently launched products and due to additional Research & Development on essential project studies.

#### Medical Nutrition

Operating income increased to \$82 million as a result of productivity gains, lower raw material costs and product mix improvements resulting from more focus on disease specific segments. The operating margin increased to 10.1% from 0.6% in 2002 or from 4.5% when \$28 million of exceptional items related to restructuring the Business Unit and other one time items are excluded from the 2002 operating income.

#### Infant & Baby

2003 operating income rose 12% to \$254 million. Operating margin increased to 18.7% from 17.0% in 2002 when there were \$27 million of impairment charges on some of our South American operations' goodwill and intangible assets due to non-achievement of performance expectations.

## CIBA Vision

Operating income reached \$153 million, an increase of 30% over the year. This operational result was achieved due to the margin on the additional net sales and reduction in structural costs, partially offset by increased investment in advertising and promotion activities and a \$22 million charge for asset impairments related to the planned disposal of the refractive surgery activities. Operating margin increased to 11.7% in 2003 compared with 10.4% in 2002.

# Divested Health & Functional Food activities in 2002

The 2002 operating income of \$140 million includes a divestment gain of \$132 million after related restructuring charges arising on the divestment of our former Food & Beverage business. In addition there was a net \$8 million operating income from these activities after taking into account \$18 million of goodwill impairment charges necessary due to the divestment.

# Corporate Income, net

Net corporate income totaled \$146 million, \$31 million more than in the prior year. Higher income from charging share and share option plan costs to the operations and the settlement of a litigation for \$41 million less than the provision, more than offset increased investments in Corporate research, the negative currency translation effects on non-US dollar costs, and lower pension income.

# 5. Net income

The following table sets forth selected income statement data for the periods indicated.

	Year ended December 31,			
	2003	2002	Change in \$	
Operating income	(\$ millions) 5,889	(\$ millions) 5,092	(%) 16	
Results from associated companies Financial income, net	(200) 379	(7) 613	(38)	
Income before taxes and minority interests	<b>6,068</b> (1,008)	<b>5,698</b> (959)	<b>6</b> 5	
Income before minority interests	<b>5,060</b> (44)	<b>4,739</b> (14)	7	
Net income	5,016	4,725	6	

#### **Results from associated companies**

Associated companies are accounted for using the equity method where we generally own between 20% and 50% of the voting shares of such companies. Income from associated companies is mainly derived from our investments in Roche Holding AG and Chiron Corporation.

Our 42% interest in Chiron contributed pre-tax income of \$134 million (2002: \$107 million). Our 33.3%, just under one third (2002: 32.7%) interest in Roche voting shares, which represented a 6.3% (2002: 6.2%) interest in the total Roche equity instruments generated a pre-tax loss of \$354 million (2002: \$116 million loss), \$269 million of which was due to our share in Roche's unexpected loss of CHF 4.0 billion in 2002, booked only in 2003. The remainder represents an estimate of our share (\$185 million) in Roche's 2003 pre-tax income. This share of pre-tax income is reduced by a \$270 million goodwill and intangible depreciation charge arising from allocating the purchase price to property, plant and equipment, intangible assets and goodwill.

Our share of the net income of both Roche and Chiron was based upon analysts' estimates. Differences between these estimates and actual results were adjusted in 2004. In total, associated companies resulted in an overall expense of \$200 million in 2003 (2002: \$7 million).

# Financial income, net

Amid persistently challenging equity market conditions, lower interest rates and a lower level of average net liquidity than in the prior year, net financial income declined 38% or \$234 million. See Item 11 for a discussion of our risk management policy, the employment of financial instruments and their accounting.

The following table provides an analysis of our sources of net financial income:

	Equity options	Forward exchange contracts	Foreign exchange options	Interest Rate Swaps/Cross Currency Swaps/ Forward Rate Agreements	Total
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
2003					
Income on options and forward contracts	270	185	331	327	1,113
Expenses on options and forward contracts	<u>(419</u> )	<u>(140</u> )	(250)		(809)
Options and forward contracts results, net	(149)	45	81	327	304
Net interest					80
Dividend income					17
Net capital gains					11
Impairment of marketable securities					(66)
Other financial result, net					(31)
Currency result, net					64
Total financial income, net					379

	Equity options (\$ millions)	Bond options (\$ millions)	Forward exchange contracts (\$ millions)	Foreign exchange options (\$ millions)	Interest Rate Swaps/Cross Currency Swaps/ Forward Rate <u>Agreements</u> (\$ millions)	Total (\$ millions)
2002						
Income on options and forward contracts Expenses on options and forward contracts	1,180 (942)	7 (11)	136 (53)	256 (255)	80	1,659 (1,261)
<b>Options and forward contracts</b>				<u> </u>		<u> </u>
results, net	238	(4)	83	1	80	398
Net interestDividend incomeNet capital lossesOther financial result, netCurrency result, netTotal financial income, net						222 68 (79) (65) <u>69</u> <b>613</b>
iotai iinanciai income, net						013

#### Taxes

Despite increased profits, the tax charge of \$1.0 billion increased only \$49 million over the prior year. Our effective tax rate (taxes as a percentage of income before tax) was 16.6% in 2003 compared to 16.8% in 2002.

Our expected tax rate (weighted average tax rate based on the result before tax of each subsidiary) was 14.8% in 2003 compared to 15.3% in 2002. Our effective tax rate was is different from the expected tax rate due to the income statement effects of equity accounting for associated companies of 1.9% (2002: 0.3%) and various adjustments to expenditures and income for taxation purposes. For details of the main elements contributing to the difference, see note 6 to the consolidated financial statements.

# Net income

Net income as a percentage of total net sales decreased from 22.6% in 2002 to 20.2% in 2003 principally due to lower financial income and the negative impact of the results of associated companies.

Return on average equity decreased from 17.7% in 2002 to 17.1% in 2003.

### **Exchange Rate Exposure and Risk Management**

We transact our business in many currencies other than the US dollar, our reporting currency. As a result of our foreign currency exposure, exchange rate fluctuations have a significant impact in the form of both translation risk and transaction risk on our income statement. Translation risk is the risk that the our consolidated financial statements for a particular period or as of a certain date may be affected by changes in the prevailing rates of the various currencies of the reporting subsidiaries against the US dollar. Transaction risk is the risk that the value of transactions executed in currencies other than the subsidiary's measurement currency may vary according to currency fluctuations.

In 2004, 43% of net sales were generated in US dollars, 26% in euro, 3% in Swiss francs, 8% in yen and 20% in other currencies. In 2003, 43% of net sales were generated in US dollars, 26% in euro, 4% in Swiss francs, 8% in yen and 19% in other currencies. In 2002, 43% of our net sales were generated in US dollars, 25% in euro, 5% in Swiss francs, 8% in yen and 19% in other currencies.

In 2004, 37% of operating costs were generated in US dollars, 23% in euro, 15% in Swiss francs, 5% in yen, and 20% in other currencies. In 2003, 41% of operating costs were generated in US dollars, 23% in euro, 17% in Swiss francs, 4% in yen, and 15% in other currencies. In 2002, 41% of our operating costs were generated in US dollars, 22% in euro, 22% in Swiss francs, 4% in yen, and 11% in other currencies.

#### **New Accounting Pronouncements**

See note 32(m)(xii) and (xiii) to the consolidated financial statements for a discussion of the effect of new accounting standards.

### 5.B Liquidity and Capital Resources

### **Cash Flow**

The following table sets forth certain information about our cash flow and net liquidity for each of the periods indicated.

	Year ended December 31,			
	2004	2003	2002	
	(\$ millions)	(\$ millions)	(\$ millions)	
Cash flow from operating activities	6,725	6,652	5,229	
Cash flow used for investing activities	(3,219)	(1,298)	(2,865)	
Cash flow used for financing activities	(3, 124)	(5,764)	(4,041)	
Net effect of currency translation on cash and cash				
equivalents	55	258	836	
Change in cash and cash equivalents	437	(152)	(841)	
Change in short- and long-term marketable securities	897	869	189	
Change in short- and long-term financial debts	(885)	(400)	(402)	
Change in net liquidity	449	317	(1,054)	
Net liquidity at January 1	7,289	6,972	8,026	
Net liquidity at December 31	7,738	7,289	6,972	

The analysis of our cash flow is divided as follows:

- 1. Cash flow from Operating Activities and Free Cash Flow
- 2. Cash flow used for Investing Activities
- 3. Cash flow used for Financing Activities
- 4. Net Liquidity

#### 1. Cash Flow From Operating Activities and Free Cash Flow

Our primary source of liquidity is cash generated from our operations. In 2004, cash flow from operating activities increased by \$73 million (1%) to \$6.7 billion. Depreciation, amortization and impairment charges remained at the prior year level of \$1.4 billion, while current tax payments rose \$241 million compared to the previous year.

In 2003, the cash flow from operating activities increased by \$1.4 billion (27%) from 2002 to \$6.7 billion mainly as result of improved working capital management and higher net income.

Depreciation, amortization and impairment charges increased from 2002 by \$50 million to \$1.4 billion. Tax payments in 2003 were \$49 million higher than the prior year.

Our free cash flow, excluding the impact of the acquisitions or divestments of subsidiaries, associated companies and minority investments decreased 7% to \$3.4 billion in 2004 from \$3.6 billion in 2003. The free cash flow increased 23% from \$3.0 billion in 2002 to \$3.6 billion in 2003.

Our capital expenditure on property, plant and equipment for 2004 and 2003 totaled \$1.3 billion (4.5% of net sales in 2004 and 5.3% of net sales in 2003), compared to \$1.1 billion in 2002 (5.3% of net sales).

This level of capital expenditure reflects the continuing investment in Production as well as Research and Development facilities. We expect to maintain spending at approximately the 2004 percentage of sales levels in 2005 and to fund these expenditures with internally generated resources.

We present Free Cash Flow as additional information as it is a useful indicator of our ability to operate without reliance on additional borrowing or usage of existing cash. Free Cash Flow is a measure of the net cash generated which is available for debt repayment and investment in strategic opportunities, including strengthening our balance sheet. We use Free Cash Flow in internal comparisons of our Divisions' and Business Units' results. Free Cash Flow of our Divisions and Business Units uses the same definition as that for our Group, however no dividends, tax or financial receipts or payments are included in the Division and Business Unit calculation. Free Cash Flow is not intended to be a substitute measure for cash flow from operating activities (as determined under IFRS or US GAAP).

The following table details the components of these increases.

	Year ended December 31,			
	2004	2003	2002	
	(\$ millions)	(\$ millions)	(\$ millions)	
Cash flow from operating activities	6,725	6,652	5,229	
Purchase of property, plant & equipment fixed assets	(1, 269)	(1, 329)	(1,068)	
Purchase of intangibles assets	(181)	(214)	(90)	
Purchase of financial assets	(747)	(816)	(725)	
Proceeds from sale of property, plant & equipment,				
intangible and financial assets	799	1,059	979	
Dividends paid to third parties	(1,968)	(1,724)	(1,367)	
Free cash flow	3,359	3,628	2,958	

# 2. Cash Flow used for Investing Activities

In 2004, cash outflow due to investing activities was \$3.2 billion. A total of \$1 billion was spent on acquisitions, while investments in property, plant & equipment amounted to \$1.3 billion. The net payments for acquiring marketable securities was \$0.8 billion and other investments accounted for \$0.1 billion.

In 2003, our cash outflow due to investing activities was \$1.3 billion. \$0.4 billion was spent to increase the strategic investment in Roche and for the acquisition of Idenix. Our investment in property, plant and equipment totaled \$1.3 billion. The net proceeds from sales of marketable securities was \$0.4 billion.

In 2002, our net cash outflow from investing activities was \$2.9 billion. Thereof \$2.7 billion was spent to increase the strategic investment in Roche and for the acquisition of Lek.

#### 3. Cash Flow used for Financing Activities

Cash flow used for financing activities in 2004 was \$3.1 billion, down \$2.6 billion from 2003. \$1.9 billion was spent on the acquisition of treasury shares and \$2.0 billion on dividend payments. \$0.8 billion was due to the increase in short and long-term financial debt and a capital inflow from the IPO of Idenix Inc.

In 2003, the cash flow used for financing activities was \$5.8 billion. \$0.3 billion was spent for the acquisition of treasury shares, \$1.7 billion for dividend payments and \$3.5 billion for the repayment of equity instruments.

Our net cash outflow used for financing activities was \$4.1 billion in 2002. In 2002, \$3.3 billion was spent for the acquisition of treasury shares and \$1.4 billion for dividend payments while the issue of a EUR 1 billion bond and the conversions of the remaining two convertible bonds contributed to a net inflow of \$0.6 billion.

#### 4. Net Liquidity

Overall liquidity (cash, cash equivalents and marketable securities including financial derivatives) amounted to \$14.6 billion at December 31, 2004. Net liquidity (liquidity less financial debt) at year-end was \$7.7 billion an increase of \$0.4 billion from December 31, 2003.

Our overall liquidity amounted to \$13.3 billion at December 31, 2003. Net liquidity at year end was \$7.3 billion, \$0.3 billion more than at December 31, 2002.

We present overall liquidity and net liquidity as additional information as they are useful indicators of our ability to meet our financial commitments and to invest in new strategic opportunities, including strengthening our balance sheet. These items should not be interpreted as measures determined under IFRS.

We use marketable securities and derivative financial instruments to manage the volatility of our exposures to market risk in interest rates and liquid investments. Our objective is to reduce, where appropriate, fluctuations in earnings and cash flows. We manage these risks by selling existing assets or entering into transactions and future transactions (in the case of anticipatory hedges) which we expect we will have in the future, based on past experience. We therefore expect that any loss in value for those securities or derivative financial instruments generally would be offset by increases in the value of those hedged transactions.

We use the US dollar as our reporting currency and are therefore exposed to foreign exchange movements primarily in European, Japanese and other Asian and Latin American currencies. We manage the risk associated with currency movements by entering into various contracts to preserve the value of assets, commitments and anticipated transactions. In particular, we enter into forward contracts and foreign currency option contracts to hedge certain anticipated foreign currency revenues in foreign subsidiaries. See "Item 11. Quantitative and Qualitative Disclosures About Market Risk," for additional information.

# Share repurchase program

In August 2004, we announced the completion of the third share-repurchase program and the start of a fourth program to repurchase shares via a second trading line on the SWX Swiss Exchange for approximately \$2.4 billion (CHF 3.0 billion). In 2004, a total of 22.8 million shares were repurchased for \$1.0 billion to complete the third repurchase program. Since the start of the fourth program, a total of 15.2 million shares have been repurchased for \$0.7 billion. Overall in 2004, a total of 41 million shares have been repurchased for \$1.9 billion, which includes shares bought through the repurchase programs and additional shares bought on the first trading line. A proposal will be made at the Annual General Meeting on March 1, 2005 to reduce the share capital by 38.0 million shares bought through the purchase

programs on the second trading line and to initiate a fifth share repurchase program for approximately \$3.5 billion (CHF 4.0 billion).

In 2004, our share capital was reduced by 24.3 million shares relating to shares bought on the second trading line in 2003.

On July 22, 2002, we initiated our third share buy-back program to repurchase shares on the SWX Swiss Exchange for up to a total of CHF 4 billion. During 2003, 24.3 million shares were repurchased via a second trading line for a total amount of \$939 million (2002: 24.6 million shares for a total amount of \$1.0 billion). In 2003, the Group's share capital was reduced by 22.7 million shares relating to shares bought on the second trading line in 2002.

During the year to December 31, 2003 an additional 17.1 million shares, net, were also sold on the first trading line for a total of \$666 million (2002: 55.4 million shares, net were bought for \$2.4 billion).

At December 31, 2004, our holding of treasury shares (excluding the amount that we will propose to be cancelled at the March 1, 2005 Annual General Meeting) under IFRS amounted to 312 million shares or 11% of the total number of issued shares.

### Other equity instruments

During December 2001, through indirectly held affiliates, we sold a total of 55 million ten-year call options (Low Exercise Price Options—"LEPOs") on our shares, with an exercise price of CHF 0.01, for EUR 2.2 billion in proceeds (EUR 40 per LEPO). We accounted for the LEPOs as an increase in share premium at fair value less related issuance costs. Following changes in US GAAP and expected changes in IFRS, on June 26, 2003 we redeemed these equity instruments in advance of their exercise date.

We had previously also sold a total of 55 million nine and ten-year put options on our shares to a third party with an exercise price of EUR 51 receiving EUR 0.6 billion in proceeds (EUR 11 per put option). We accounted for the option premium associated with the put options as an increase in share premium less related issuance costs. Following changes in US GAAP and expected changes in IFRS, on June 26, 2003 we redeemed these equity instruments in advance of their exercise date.

### Straight Bonds

On November 14, 2002, our affiliate, Novartis Securities Investment Ltd, Bermuda, issued a 3.75% bond, guaranteed by Novartis AG and due in 2007, in the amount of EUR 1 billion.

On October 17, 2001, our affiliate, Novartis Securities Investment Ltd., Bermuda, issued a 4% bond, guaranteed by Novartis AG and due in 2006, in the amount of EUR 900 million.

# **Direct Share Purchase Plans**

Since 2001 Novartis has been offering US investors the ADS Direct Plan, which provides investors in the United States an easy and inexpensive way of directly purchasing Novartis stock and of reinvesting dividends. This plan holds Novartis American Depositary Shares (ADSs) which are listed on the New York Stock Exchange under the trading symbol NVS. At the end of 2004, the US Direct Share Purchase Plan had 332 participants. Since September 1, 2004 Novartis also offers a Direct Share Purchase Program to investors residing in Switzerland, Liechtenstein, France and the United Kingdom, which is the first of its kind in Europe. With this plan Novartis offers an easy and inexpensive way of directly purchasing Novartis registered shares and of depositing them free of charge with SAS SIS Aktienregister AG. As of December 31, 2004, a total of 8,862 shareholders were or had been enrolled in this program.

#### 5.C Research & Development, Patents and Licenses

Our Research & Development spending totaled \$4.2 billion, \$3.8 billion and \$2.8 billion for the years 2004, 2003 and 2002, respectively. Each of our Divisions and Business Units has its own Research &

Development and patents policies. For a description of those research and development and patents policies, see "Item 4. Information on the Company—4.B Business Overview."

# 5.D Trend Information

Please see "-5.A Operating Results" and "Item 4. Information on the Company-4.B Business Overview" for trend information.

### 5.E Off-Balance Sheet Arrangements

We have no unconsolidated special purpose financing or partnership entities or other off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, that is material to investors. See also notes 27 and 28 of the consolidated financial statements and matters described in Item 5.F, "Aggregate Contractual Obligations—Contingencies".

### 5.F Aggregate Contractual Obligations

We have long-term research agreements with various institutions which require us to fund various research projects in the future. As of December 31, 2004, the aggregate total amount of payments, including potential milestones, which may be required under these agreements was \$1.2 billion. We expect to fund these long-term research agreements with internally generated resources.

As of December 31, 2004, our total financial debt was \$6.9 billion, as compared with \$6.0 billion as of December 31, 2003, and \$5.6 billion as of December 31, 2002.

The increase from 2003 to 2004 was primarily due to new repurchase agreements of \$709 million and currency translation effects on our euro denominated bonds of \$213 million. The increase from 2002 to 2003 is due to currency translation effect on our euro denominated bonds. Our year end debt/equity ratio remained stable at 0.20:1 in 2004 (No change in ratio from 2003 and 2002).

We had \$3.2 billion in non-convertible bonds at December 31, 2004, up from \$3.0 billion at December 31, 2003 and \$2.6 billion as of December 31, 2002. The increases in 2004 and 2003 have been due to currency translation effect on our euro denominated bonds.

For details on the maturity profile of debt, currency and interest rate structure, see note 18 to the consolidated financial statements.

As of December 31, 2004, we had short-term debt (excluding the current portion of long-term debt) of \$3.4 billion as compared with \$2.7 billion as of December 31, 2003, and \$2.7 billion as of December 31, 2002.

This short-term debt consisted mainly of \$0.7 billion in repurchase agreements created in 2004; \$0.4 billion (2003: \$0.6 billion; 2002 \$0.9 billion) commercial paper; and other bank and financial debt, including interest bearing employee accounts, of \$2.1 billion (2003: \$1.6 billion; 2002: \$1.5 billion).

We are in compliance with all covenants or other requirements set forth in our financing agreements. We do not have any rating downgrade triggers that would accelerate maturity of our debt. For details of the maturity profile of debt, currency and interest rate structure, see note 18 to the consolidated financial statements. Our debt continues to be rated by Standard & Poor's and Moody's respectively as AAA and Aaa for long-term maturities and A1+ and P1 for short-term debt. We consider our financial resources and facilities to be sufficient for our present requirements.

	Payments Due by Period						
Contractual Obligations	Total (\$ millions)	Less than 1 year (\$ millions)	2-3 years (\$ millions)	4-5 years (\$ millions)	After 5 years (\$ millions)		
Long-Term Debt	3,416	680	2,676	36	24		
Operating Leases	926	233	304	143	246		
Research & Development Commitments —unconditional	665	285	245	112	22		
	665 582	283 91	245 158	113 200	22 133		
Purchase commitments —property,plant &	502	71	150	200	155		
equipment	325	241	66	18			
—other assets	57	28	29				
<b>Total Contractual Cash</b>							
Obligations	5,971	1,558	3,478	510	425		

### **Contingencies**

In connection with our original investment in January 1996 in Chiron:

- We have agreed to purchase up to \$500 million of new Chiron equity at fair value, at Chiron's request. To date, Chiron has made no such request.
- We have agreed to guarantee up to \$703 million of Chiron debt. Utilization of the guarantee in excess of \$403 million reduces the equity put amount mentioned above. Our obligation under the guarantee is only effective if Chiron defaults on the debt.
- Chiron has granted to us an option to purchase newly issued shares of equity securities directly from Chiron at fair market value. We may exercise this option at any time subject to certain conditions, including a limitation on our aggregate ownership not to exceed 55% of Chiron's then outstanding common stock.

The outstanding equity put and guarantee expire no later than 2011.

For other contingencies, see "Item 4. Information on the Company—4.D Property, Plants and Equipment—Environmental Matters" and "Item 8. Financial Information—8.A Consolidated Statements and Other Financial Information—8.A.7 Legal Proceedings."

#### Item 6. Directors, Senior Management and Employees

#### 6.A Directors and Senior Management

#### Directors

Members of the Board of Directors

	Age	Director Since	Term Expires
Daniel Vasella, M.D.	51	1996	2007
Helmut Sihler, J.D., Ph.D.	74	1996	2007
Hans-Joerg Rudloff	64	1996	2007
Dr. h.c. Birgit Breuel	67	1996	2005
Peter Burckhardt, M.D.	66	1996	2005
Srikant Datar, Ph.D	51	2003	2006
William W. George	62	1999	2006
Alexandre F. Jetzer	63	1996	2005
Pierre Landolt	57	1996	2005
Ulrich Lehner, Ph.D.	58	2002	2005
DrIng. Wendelin Wiedeking	52	2003	2006
Rolf M. Zinkernagel, M.D.	60	1999	2006

*Daniel Vasella, M.D. Swiss, age 51.* Since 1996 Daniel Vasella has served as President and Chairman of the Group Executive Committee (CEO). In 1999, he additionally was appointed Chairman of the Board of Directors. He is an executive director. Daniel Vasella is also a member of the Board of Directors of Pepsico, Inc., US. He is a member of the Board of Directors of Associates of Harvard Business School. Daniel Vasella graduated with an M.D. from the University of Bern in 1979. After holding a number of medical positions in Switzerland, he joined Sandoz Pharmaceuticals Corporation in the US in 1988. From 1993 to 1995, Daniel Vasella advanced from Head of Corporate Marketing and Senior Vice President and Head of Worldwide Development to Chief Operating Officer of Sandoz Pharma Ltd. In 1995 and 1996, Daniel Vasella was a member of the Sandoz Group Executive Committee and Chief Executive Officer of Sandoz Pharma Ltd. In 2002, Dr. Vasella was awarded an honorary doctorate by the University of Basel. Daniel Vasella is a member of the Chairman's Council of DaimlerChrysler AG, Germany. In addition, he is President of the International Federation of Pharmaceutical Manufacturers Associations, a member of the International Board of Governors of the Peres Center for Peace in Israel and a member of the International Business Leaders Advisory Council for the Mayor of Shanghai. He also serves as a member of several industry associations and educational institutions.

*Helmut Sihler, J.D., Ph.D. Austrian, age 74.* Helmut Sihler became Vice Chairman in 1996. He became Lead Director in 1999 and is a member of the Chairman's Committee and the Corporate Governance Committee. He chairs the Audit and Compliance Committee and the Compensation Committee. He qualifies as a Non-Executive, independent Director and the Board has decided that he is adequately qualified in financial matters in accordance with applicable Regulations to chair the Audit and Compliance Committee. Helmut Sihler is Chairman of the Supervisory Board of Dr.-Ing. h.c. F. Porsche AG, Germany. Helmut Sihler studied philology and law in Graz, Austria and Burlington, Vermont (US) and graduated with a Ph.D. in philology and a J.D. In 1957, he joined Henkel KGaA, Germany, initially holding several positions in the marketing department for consumer goods. From 1980 to 1992, Helmut Sihler was Chairman of the Central Board of Management of Henkel KGaA. In 1988 and 1989, Helmut Sihler was President of the Association of the German Chemical Industry. Helmut Sihler was ad interim CEO of Deutsche Telekom AG, Germany, from July to November 2002.

Hans-Joerg Rudloff German, age 64. Since 1996 Hans-Joerg Rudloff has served as Vice Chairman. In 1999, he became a member of the Chairman's Committee and the Compensation Committee and since 2002 he has been a member of the Corporate Governance Committee. He qualifies as an independent Non-Executive Director. Since 2004 Hans-Joerg Rudloff has been a member of the Audit and Compliance Committee. Hans-Joerg Rudloff joined Barclays Capital in 1998, where he is presently Chairman of the Executive Committee. Hans-Joerg Rudloff also serves on a number of boards of other companies, including the Boards of Directors of the TBG Group (Thyssen-Bornemisza Group), Monaco, Marcuard Group, Geneva, RBC, Russia and ADB Consulting, Geneva, Switzerland. Hans-Joerg Rudloff studied economics at the University of Bern and graduated in 1965. He joined Credit Suisse in Geneva and moved to New York in 1968 to join the investment banking firm of Kidder Peabody Inc. He was in charge of Kidder Peabody's Swiss operation and was elected Chairman of Kidder Peabody International and a member of the Board of Kidder Peabody Inc. in 1978. In 1980 he joined Credit Suisse First Boston and was elected Vice Chairman in 1983 and Chairman and CEO in 1989. From 1986 to 1990 Hans-Joerg Rudloff was also a member of the Executive Board of Credit Suisse in Zurich in charge of all securities and capital market departments. From 1994 to 1998 Hans-Joerg Rudloff was Chairman of MC-BBL in Luxembourg. In 1994, Hans-Joerg Rudloff was elected to the Board of Directors of Sandoz AG. Hans-Joerg Rudloff is a member of the Advisory Board of the MBA program of the University of Bern, Switzerland and of Landeskreditbank Baden-Württemberg, Germany, and EnBW (Energie Baden-Württemberg), Germany.

*Dr. h.c. Birgit Breuel German, age 67.* Since 1996 Birgit Breuel has served as a Member of the Board. In 1999, she became a member of the Audit and Compliance Committee. She qualifies as an independent, Non-Executive Director. Birgit Breuel is also a member of the Supervisory Board of Gruner+Jahr AG, Hamburg,Germany, of WWF, Germany, and of HGV (Hamburger Gesellschaft für Vermögens-und Beteiligungsverwaltung mbH), Germany. Birgit Breuel studied politics at the Universities of Hamburg, Oxford and Geneva. She was Minister of Economy and Transport (1978-1986) and Minister of Finance (1986-1990) of Niedersachsen (Lower Saxony), the second largest state of Germany. In 1990, Birgit Breuel was elected to the Executive Board of the Treuhandanstalt, which was responsible for the privatization of the former East Germany's economy; in 1991, she also became the President of the Treuhandanstalt. From 1995 to 2000, she acted as the General Commissioner and CEO of the world exhibition EXPO 2000 in Hanover, Germany.

Peter Burckhardt, M.D. Swiss, age 66. Peter Burckhardt has been a member of the Board of Directors since 1996. He qualifies as an independent, Non-Executive Director. From 1982 to 2004, Peter Burckhardt has been the Chairman of the Novartis (formerly Sandoz) Foundation for Biomedical Research in Switzerland. After studying in Basel and Hamburg, Peter Burckhardt graduated with an M.D. from the University of Basel in 1965. He trained from 1966 to 1978 in internal medicine and endocrinology, mainly at the University Hospital of Lausanne, Switzerland, and the Massachusetts General Hospital, Boston, US. Peter Burckhardt was appointed Chief of Clinical Endocrinology in 1978, and full Professor of Internal Medicine and Chairman of the Department of Internal Medicine at the University Hospital of Lausanne in 1982. In addition to his activities as a clinician and academic teacher, Peter Burckhardt conducs clinical research, mainly in bone diseases and calcium metabolism. He has authored more than 300 scientific publications and is an editorial board member of several international scientific journals. He was president of the Swiss Society of Internal Medicine, a member of the appeal committee of the national agency for drug controls and a board member of numerous scientific societies including the Swiss Societies of Nutrition, Clinical Chemistry, Endocrinology, Bone and Mineral Research, and the Committee for Endocrinology of the European Community. Since 1982, Peter Burckhardt has been the Head of the Department of Internal Medicine at the University Hospital of Lausanne, then chief of medical service until 2004. He is treasurer of the International Foundation of Osteoporosis. Since 1990, he has been the organizer and chairman of the International Symposia on Nutrition and Osteoporosis.

*Srikant Datar, Ph.D. Indian, age 51.* Srikant Datar became a member of the Board in 2003. He is a Non-Executive Director. Srikant Datar is a member of the Board of Voyan Technology Inc., Santa Clara, California, and of Harvard Business School Interactive, Boston, Massachusetts. In 1973, Professor Srikant

Datar graduated with distinction in mathematics and economics at the University of Bombay. He is a Chartered Accountant and holds two masters degrees and a Ph.D. from Stanford University. Professor Datar has worked as an accountant and planner in industry and as a Professor at the Universities of Carnegie Mellon, Stanford and Harvard in the US. He currently holds the Arthur Lowes Dickinson Professorship at Harvard University. His research interests are in the areas of cost management, measurement of productivity, new product development, time-based competition, incentives and performance evaluation. He is the author of many scientific publications and has received several academic awards and honors. Srikant Datar has advised and worked with numerous renowned firms such as Du Pont, General Motors and Mellon Bank in research, development and training. Srikant Datar is Senior Associate Dean for Executive Education at the Graduate School of Business Administration of Harvard University. Boston, Massachusetts.

*William W. George American, age* 62. In 1999, William W. George was elected as a member of the Board of Directors. In 2001, he became a member of the Chairman's Committee and the Chairman of the Corporate Governance Committee. He qualifies as an independent, Non-Executive Director. William W. George is a member of the Boards of Directors of Goldman Sachs and Target Corporation (formerly Dayton Hudson), Minneapolis. William W. George received his BSIE from Georgia Institute of Technology in 1964 and his MBA from Harvard University in 1966. From 1966 to 1969, he worked in the US Department of Defense as special assistant to the Secretary of the Navy and as assistant to the Comptroller. After having served as President of Litton Microwave Cooking Products, William W. George held a series of executive positions with Honeywell from 1978 to 1989. Thereafter he served as President and Chief Operating Officer of Medtronic, Inc. in Minneapolis, and, from 1991 to 2001, as its Chief Executive Officer. From 1996 to 2002, he was Medtronic's Chairman. He has served as Executive-in-Residence at Yale School of Management and Professor of Leadership and Governance at IMD International in Lausanne, Switzerland. William W. George is Professor of Management Practice at Harvard Business School, In addition, he is a member of the Board of Directors of the National Peace.

*Alexandre F. Jetzer Swiss, age 63.* Alexandre F. Jetzer has served as a Director since 1996. He is a Non-Executive Director. Alexandre F. Jetzer is also a member of the Board of Directors of Clariden Bank, Zurich, Switzerland, of the Supervisory Board of Compagnie Financière Michelin, Granges-Paccot (FR), Switzerland, and of the Board of the Lucerne Festival Foundation, Lucerne, Switzerland. Alexandre F. Jetzer graduated with Masters of law and economics from the University of Neuchâtel, Switzerland and is a licensed attorney. After serving as General Secretary of the Swiss Federation of Commerce and Industry (Vorort) from 1967 on, Alexandre F. Jetzer joined Sandoz in 1980. In 1981 he was appointed Member of the Sandoz Group Executive Committee in the capacity of Chief Financial Officer (CFO) and, as of 1990, as Head of Management Resources and International Coordination. From 1995 to 1996, he was Chairman and Chief Executive Officer of Sandoz Pharmaceuticals Corporation in East Hanover, New Jersey (US) and he additionally was appointed President and CEO of Sandoz Corporation in New York (NY). After the merger which created Novartis in 1996 until 1999, he served as a member of the Novartis Group Executive Committee and Head of International Coordination, Legal & Taxes. Mr. Jetzer continues to support our Government Relations activities under a Consultancy Agreement.

*Pierre Landolt Swiss, age 57.* Pierre Landolt has served as a Director since 1996. He qualifies as an independent, Non-Executive Director. Pierre Landolt is the President of the Sandoz Family Foundation, Glaris, Switzerland, and the Chairman of the Board of Directors of Landolt Kapital SA, Pully, Switzerland, and of Emasan AG, Basel, Switzerland. He is also a member of the Board of Directors of Syngenta AG, and of the Syngenta Foundation for Sustainable Agriculture, both in Basel, Switzerland. In addition, he serves as Chairman of the Board of Directors of Curacao International Trust Company, Curacao, Netherlands Antilles, Vaucher Manufacture Fleurier SA., Fleurier, Switzerland (Chairman), and as Vice Chairman of the Boards of Directors of Parmigiani, Mesure et Art du Temps S.A., Fleurier, Switzerland, and the Fondation du Montreux Jazz Festival, Montreux, Switzerland. Pierre Landolt graduated with a Bachelor of Law degree from the University of Paris-Assas. From 1974 to 1976, he worked for Sandoz Brazil. In 1977, he acquired an agricultural estate in Brazil, cultivating organic tropical

fruit as well as producing dairy products. In 1989, he founded a firm for irrigation systems. In the same year, he became the main associate and director of a bank in São Paulo. Since 1997 Pierre Landolt has been Associate and Chairman of Axial Par Ltda, São Paulo, a company investing in sustainability. In 2000, he was co-founder of Eco Carbone LLC, Delaware, US, a company focused on the development of carbon sequestration processes in Europe, Africa and South America.

*Ulrich Lehner, Ph.D. German, age 58.* Ulrich Lehner was elected to the Board of Directors of Novartis AG in 2002. He is a member of the Audit and Compliance Committee. The Board has appointed him as Audit Committee Financial Expert. He qualifies as an independent Non-Executive Director. Ulrich Lehner is President and CEO of Henkel KGaA, Germany. He also serves as a member of the Board of Ecolab Inc., St. Paul, US, as member of the supervisory board of E.ON AG and of HSBC Trinkaus & Burkhardt KGaA, both in Düsseldorf, Germany. Ulrich Lehner studied business administration and mechanical engineering. From 1975 to 1981, Ulrich Lehner was an auditor with KPMG Deutsche Treuhand-Gesellschaft AG in Düsseldorf. In 1981, he joined Henkel KGaA. After heading the Controlling Department of Fried. Krupp GmbH in Essen, Germany, from 1983 to 1986, he returned to Henkel KGaA as Finance Director. From 1991 to 1994, Ulrich Lehner headed the Management Holding Henkel Asia-Pacific Ltd. in Hong Kong. From 1995 to 2000, he served Henkel KGaA, Düsseldorf, as Executive Vice President, Finance/Logistics (CFO). Ulrich Lehner is a member of the Advisory Board of Dr. August Oetker KG, Bielefeld, Germany, and of Krombacher Brauerei, Krombach, Germany. He is an Honorary Professor at the University of Münster, Germany.

*Dr.-Ing. Wendelin Wiedeking German, age* 52. Wendelin Wiedeking was elected as a member of the Board in 2003. He qualifies as an independent, Non-Executive Director. Wendelin Wiedeking is Chairman of the Executive Board of Dr.-Ing. h.c. F. Porsche AG, Germany, and a member of the Supervisory Board of Directors of Deutsche Telekom AG, Germany, and of Eagle Picher Incorporated, Phoenix, Arizona. Born in Ahlen, Germany, Wendelin Wiedeking studied mechanical engineering and worked as a scientific assistant in the Machine Tool Laboratory of the Rhine-Westphalian College of Advanced Technology in Aachen. His professional career began in 1983 as Director's Assistant in the Production and Materials Management area of Dr.-Ing. h.c. F. Porsche AG in Stuttgart-Zuffenhausen. In 1988 he moved to the Glyco Metall-Werke KG in Wiesbaden as Division Manager, where he advanced by 1990 to the position of Chief Executive and Chairman of the Board of Management of Glyco AG. In 1991 he returned to Porsche AG as Production Director. A year later, the Supervisory Board appointed him spokesman of the Executive Board (CEO), and in 1993 its Chairman.

Rolf M. Zinkernagel, M.D. Swiss, age 60. In 1999, Rolf M. Zinkernagel was elected to the Board of Directors of Novartis AG. He has been a member of the Corporate Governance Committee since 2001. He qualifies as an independent, Non-Executive Director. Rolf M. Zinkernagel graduated from the University of Basel with an M.D. in 1970. Since 1992 he has been Professor and Director of the Institute of Experimental Immunology at the University of Zurich. Rolf M. Zinkernagel has received many awards and prizes for his work and contribution to science, the most prestigious being the Nobel Prize for Medicine which he was awarded in 1996. Rolf M. Zinkernagel was a member of the Board of Directors of Cytos Biotechnology AG, Schlieren/Zurich, Switzerland, until April 2003. Rolf M. Zinkernagel is a member of the Swiss Society of Allergy and Immunology, the American Associations of Immunologists and of Pathologists, the ENI European Network of Immunological Institutions, the International Society for Antiviral Research, and President of the Executive Board of the International Union of Immunological Societies (IUIS). He is also a member of the Scientific Advisory Boards of: The Lombard Odier, Darier Hentsch & Cie Bank, Geneva, Switzerland; BT & T, Jersey; Bio-Alliance AG, Frankfurt, Germany; Aravis General Partner Ltd., Cayman Islands; Cytos Biotechnology AG, Schlieren/Zurich, Switzerland; Bioxell, Milan, Italy; Esbatech, Zurich, Switzerland; Novimmune, Geneva, Switzerland; Miikana Therapeutics, Fremont CA; Cancevir, Zurich, Switzerland, and Mann-Kind, Sylmar CA, US. Rolf M. Zinkernagel is also a Science Consultant to: GenPat77, Berlin/Munich, Germany; Aponetics AG, Witterswil, Switzerland; Solis Therapeutics, Palo Alto, US; Ganymed, Mainz, Germany; and Zhen-Ao Group, Dalian, China.

#### **Executive Officers and Senior Management**

Daniel Vasella, M.D. Swiss, age 51. Chairman of the Board of Directors and Chairman of the Chairman's Committee (since 1999), Chief Executive Officer and Head of the Group Executive Committee (since 1996). See "—Directors."

*Urs Bärlocher, J.D. Swiss, age 62.* Head of Legal and General Affairs and a member of the Group Executive Committee (since 1999). Urs Bärlocher earned his JD from the University of Basel and was admitted to the bar in 1970. After working as a tax lawyer, he joined Sandoz in 1973, and held a number of key positions including Head of Strategic Planning and Head of Group Reporting. In 1987, he was made a member of the Sandoz Executive Board, responsible, among other things, for Strategic Planning, HR, Legal, Taxes, Patents and Trademarks. In 1990, he became CEO of the Sandoz Nutrition Division and then, in 1993, CEO of Sandoz Pharma. In 1995, Urs Bärlocher assumed the position of Chairman of the Board of Sandoz Deutschland GmbH (Germany) and Biochemie GmbH (Austria). After the formation of Novartis in 1996 he served as Head of Legal, Tax, Insurance, to which Corporate Security and International Coordination were added. He became a member of the Executive Committee of Novartis in 1999. He has held his current position as Head of Legal and General Affairs since 2000, when his responsibilities were extended to include Corporate Intellectual Property and Corporate Health, Safety & Environment as well as, from 2004, the newly created function, Corporate Risk Management.

*Raymund Breu, Ph.D. Swiss, age 59.* Chief Financial Officer and a member of the Group Executive Committee (since 1996). Raymund Breu graduated from the Swiss Federal Institute of Technology (ETH) in Zurich, Switzerland, with a PhD in mathematics. In 1975, he joined the Treasury Department of the Sandoz Group, and, in 1982, became the Head of Finance for the Sandoz affiliates in the UK. In 1985, he was appointed Chief Financial Officer of Sandoz Corporation in New York, where he was responsible for all Sandoz Finance activities in the US. In 1990, he became Group Treasurer of Sandoz Ltd., Basel, Switzerland, and, in 1993, Head of Group Finance and Member of the Sandoz Executive Board. Following the formation of Novartis in 1996, he assumed his current position as Chief Financial Officer and member of the Group Executive Committee. Raymund Breu is also a member of the Board of Directors of Swiss Re, Chiron (US) and of the SWX Swiss Exchange and its admission panel and takeover commission.

*Paul Choffat, J.D. Swiss, age 55.* Head of Novartis Consumer Health and member of the Group Executive Committee (since 2002). Paul Choffat holds a JD from the University of Lausanne, Switzerland, and an MBA from the International Institute for Management Development in Lausanne. He started his professional career with Nestlé in Zurich, Switzerland, and London, UK. From 1981 to 1985, he was a project manager at McKinsey & Company in Zurich. Between 1987 and 1994, he held a number of leading positions at Landis & Gyr in Zug, Switzerland, where he became a member of the Executive Board and Head of the Communications Division. In 1994, he moved to Von Roll in Gerlafingen, Switzerland, as CEO. Paul Choffat joined Sandoz in 1995 as Head of Management Resources and International Coordination. He subsequently became a member of the Executive Board and was responsible for Group Planning and Organization. During the Novartis merger he headed the integration office. In 1996, he returned to line management as CEO of Fotolabo SA, Montpre-veyres-sur-Lausanne, Switzerland, where he remained for three years before becoming an entrepreneur and private investor in 1999. He rejoined Novartis in January 2002 as Head of Novartis Consumer Health and member of the Group Executive Committee.

Thomas Ebeling German, age 45. Head of Novartis Pharma (since 2000) and member of the Group Executive Committee (since 1998). Thomas Ebeling graduated from the University of Hamburg with a degree in psychology. From 1987 to 1991, he held several positions of increasing responsibility at Reemstma Germany. In 1991, he joined Pepsi-Cola Germany as Marketing Director. He became Marketing Director for Germany and Austria in 1993 and was National Sales and Franchise Director for Pepsi's retail and on-premise sales from 1994. He then served as General Manager of Pepsi-Cola Germany. In 1997, Thomas Ebeling joined Novartis as General Manager of Novartis Nutrition for Germany and Austria. After having served as CEO of Novartis Nutrition, he became CEO of Novartis

Consumer Health worldwide, and then Chief Operating Officer of Novartis Pharmaceuticals, before attaining his present position in 2000.

*Mark C. Fishman, M.D. American, age 54.* Head of Pharmaceuticals Research and a member of the Group Executive Committee (since 2002). Mark C. Fishman is a graduate of Yale College and Harvard Medical School. He completed his Internal Medicine residency, Chief residency, and Cardiology training at the Massachusetts General Hospital. He serves on several editorial boards and has worked with national policy and scientific committees including those of the National Institutes of Health (NIH) and Wellcome Trust. He has been honored with many awards and distinguished lectureships and is a Fellow of the American Academy of Arts and Sciences. Before joining Novartis, Mark C. Fishman was Professor of Medicine at Harvard Medical School and Chief of Cardiology and Director of the Cardiovascular Research Center at the Massachusetts General Hospital in Boston.

*Juergen Brokatzky-Geiger, Ph.D. German, age* 52. Head of Human Resources and Permanent Attendee to the Executive Committee. Juergen Brokatzky-Geiger graduated with a PhD in Chemistry from the University of Freiburg, Germany, in 1982. He joined Ciba-Geigy in 1983 as a Laboratory Head in the Pharmaceutical Division. After a job rotation in Summit, NJ, from 1987 to 1988 he held a number of positions of increasing responsibility, including Group Leader of Process R&D, Head of Process R&D and Head of Process Development and Pilot Plant Operations. During the merger of Ciba-Geigy and Sandoz in 1996, Juergen Brokatzky-Geiger was appointed Integration Officer of Technical Operations. Thereafter, he became the Head of Chemical and Analytical Development and, from 1999 until August 2003, he served as the Global Head of Technical R&D. Juergen Brokatzky-Geiger was appointed to his present position as Head of Human Resources on September 1, 2003.

Steven Kelmar American, age 51. Head of Public Affairs and Communications and Permanent Attendee to the Executive Committee. Steven Kelmar graduated with a Bachelor of Arts degree in Public Administration and Economics from Pennsylvania State University and spent 14 years (1979-1993) in public service in several executive positions. He was Chief of Staff to two Members of the US Congress and also worked in several legislative capacities for Members of the US Senate and the House of Representatives before his appointment by President Bush in 1990 to the position of Assistant Secretary for Legislation in the US Department of Health and Human Services. In 1993, he joined Strategic Management Association of Alexandria, Virginia. In 1997, he moved to Medtronic Inc., to become Senior Vice President of External Relations and joined Novartis as Head of Public Affairs and Communications in Febuary 2003.

Andreas Rummelt, Ph.D. German, age 48. Head of Sandoz and Permanent Attendee to the Executive Committee. Andreas Rummelt obtained his doctorate in Pharmaceutical Sciences from the University of Erlangen-Nürnberg, Germany. He received executive training in general management and leadership from the IMD in Lausanne, INSEAD in Fontainebleau, and Harvard Business School. He is a member of numerous professional associations including the International Association for Pharmaceutical Technology, the Society of the Swiss Chemical Industry and the Society of Swiss Industrial Pharmacists. Andreas Rummelt was named CEO of Sandoz effective November 1, 2004. Prior to that, he was Head, Global Technical Operations at Novartis Pharma and a member of the Pharma Executive Committee (PEC). As Head, Global Technical Operations from 1999 through 2004, Rummelt was responsible for worldwide chemical, pharmaceutical, bio-technological and supply chain operations, as well as quality operations. Before leading Global Technical Operations, Rummelt was Head of Worldwide Technical Research & Development (TRD) from 1994 to 1999, and was responsible for developing the TRD function through the merger that created Novartis in 1996. From the time he joined Sandoz in 1985 through 1994, he served in various positions in Development, first as Laboratory Head, then as Group Head and finally as Department Head in the area of Drug Delivery Systems.

# **Business Unit Heads**<sup>(1)</sup>

Name, nationality and age	Head of Business Unit	Active for Novartis since	Significant positions previously held	Education
David Epstein, B.Sc., M.B.A. American, 43	Specialty Medicines and Oncology (since 2000)	1989	Chief Operating Officer and member of the Executive Committee of Novartis Pharmaceuticals Corporation US	Bachelor of Science, Pharmacy (Rutgers University) and MBA (Columbia University)
Anthony Rosenberg B.Sc., M.Sc. British, 51	Transplantation and Immunology (since 2001)	1980	Various leading positions with Sandoz UK and Novartis Group	Bachelor of Science (University of Leicester) and Master of Science (University of London)
<b>Flemming Ørnskov</b> Danish, 46	Ophthalmics (since 2003)	2001	Head of Cardiovascular Products Group, Novartis Pharmaceuticals Corporation	M.D. (University of Copenhagen), MBA (Insead), MPH (Harvard University)
Peter Hewes B.A. Econ. British, 57	Mature Products (since 2000)	1976	Country Head of Sandoz Portugal; Regional European Head of Novartis Pharma	Bachelor of Arts, Economics (University of Reading, UK)
Larry Allgaier B.Sc. American, 46	OTC (since 2004)	2003	VP and General Manager, North America Baby Care, for Procter & Gamble	Bachelor of Science, Chemical Engineering; Christian Brothers University
George Gunn BVM&S, DVSM, MRCVS British, 54	Animal Health (since 2004)	2003	President Animal Health, Pharmacia Corp; Head Animal Health, US and Region North America, for Novartis Animal Health	Bachelor of Veterinary Medicine and Surgery from the Royal Dick School of Veterinary Studies, Edinburgh, UK
Michel Gardet M.A. Business French, 47	Medical Nutrition (since 2002)	1991	General Manager of Novartis Consumer Health, Iberia; Head of Health and Functional Nutrition Novartis	Graduate of the Ecole Supérieure de Commerce Paris
Kurt T. Schmidt B.Sc., M.B.A. American, 47	Infant & Baby (since 2004)	2002	General Manager Food for Kraft Foods, Germany; Marketing Director Wrigley Company for German-speaking Europe, Eastern Europe and the Middle East; Head of Novartis Animal Health Business Unit	Bachelor of Science (United States Naval Academy, Annapolis) and MBA (University of Chicago)
Joseph T. Mallof B.Sc., M.B.A. American, 52	CIBA Vision (since 2002)	2002	Regional President of S.C. Johnson & Son for the Americas Asia Pacific; General Manager of Procter & Gamble in Japan and the Philippines	Bachelor of Science (Purdue University) and MBA (University of Chicago)

<sup>(1)</sup> In 2004, Christian Seiwald left his position as Sandoz Business Unit Head. He was succeeded by Andreas Rummelt, who also serves as a Permanent Attendee to the Executive Committee.

#### 6.B Compensation

# **Non-Executive Directors' Compensation**

The Compensation Committee advises the Board of Directors on the compensation of the Directors other than Dr. Vasella (the Non-Executive Directors). Non-Executive Directors receive an annual retainer in an amount that varies with the Board and Committee responsibilities of the Director. Directors receive no additional fees for attending meetings or acting as committee chairs. Directors can choose to receive the annual retainer in cash, shares, or a combination thereof. Since January 1, 2003, we no longer offer share options to Directors, or grant shares to Directors in acknowledgement of business performance. Directors are reimbursed for travel and other necessary business expenses incurred in the performance of their services.

# 2004 Non-Executive Directors' Compensation

	Annual Cash Compensation (CHF)	Shares (number)
Daniel Vasella, M.D. Chairman Chairman's Committee (Chair)	(please refer table on page	
Helmut Sihler, J.D., Ph.D. Vice Chairman, Lead Director Chairman's Committee (Member) Compensation Committee (Chair) Audit and Compliance Committee (Chair) Corporate Governance Committee (Member)	979,463	_
Hans-Joerg Rudloff Vice Chairman Chairman's Committee (Member) Compensation Committee (Member) Audit and Compliance Committee (Member) <sup>(1)</sup> Corporate Governance Committee (Member)	21,321	11,837
Dr. h.c. Birgit Breuel Audit and Compliance Committee (Member)	452,870	
Peter Burckhardt, M.D.	314,554	575
Srikant Datar, Ph.D.	231,000	1,724
William W. George Chairman's Committee (Member) Compensation Committee (Member)	221.250	2.460
Corporate Governance Committee (Chair)	331,250	3,460
Alexandre F. Jetzer <sup>(2)</sup>	10,927	5,745
Pierre Landolt	106,179	4,222
Ulrich Lehner, Ph.D. Chairman's Committee (Member) <sup>(1)</sup> Audit and Compliance Committee (Member)	480,000	_
DrIng. Wendelin Wiedeking	106,127	4,222
Rolf M. Zinkernagel, M.D. <sup>(3)</sup> Corporate Governance Committee (Member)         Total	<u>346,948</u> <b>3,380,696</b>	<u>5,484</u> <b>37,269</b>
10001 ·································		

<sup>(1)</sup> Since February 24, 2004.

<sup>(2)</sup> In addition, Mr. Jetzer was paid CHF 120,000 for other consulting services.

<sup>(3)</sup> Includes CHF 250,000 for acting as the Board's delegate in the scientific advisory boards of the Genomics Institute of the Novartis Research Foundation (GNF) and the Novartis Institute for Tropical Diseases (NITD).

In 2004, Walter G. Frehner and Heini Lippuner retired from their positions as Directors. No payments were made to them in 2004.

### Ownership of Novartis Shares and Share Options by the Non-Executive Directors

In December 2003, the Board of Directors adopted a share ownership guideline, under which Non-Executive Directors are required to own at least 5,000 Novartis shares within three years after joining the Board. The total number of Novartis shares owned as of December 31, 2004, by the Non-Executive Directors and persons closely linked to them was 383,420. "Persons closely linked to them" are (i) their spouse, (ii) their children below age 18, (iii) any legal entities that they own or otherwise control, or (iv) any legal or natural person who is acting as their fiduciary.

No Non-Executive Director owned 1% or more of our outstanding shares. As of December 31, 2004, the individual ownership of Novartis shares by the Non-Executive Directors (including persons closely linked to them) was as follows:

Beneficial Owner	Number of shares owned directly or indirectly
Dr. h.c. Daniel Vasella, MD	(please refer to
	the table on
	page 138)
Helmut Sihler, J.D., Ph.D.	34,304
Hans-Joerg Rudloff	109,731
Dr. h.c. Birgit Breuel	5,000
Peter Burckhardt, M.D.	15,604
Srikant Datar, Ph.D.	5,026
William W. George	112,249
Alexandre F. Jetzer	60,621
Pierre Landolt	9,387
Ulrich Lehner, Ph.D.	5,120
DrIng. Wendelin Wiedeking	7,756
Rolf M. Zinkernagel, M.D.	18,622
Total	383,420

As of the same date, the Non-Executive Directors held a total of 293,683 Novartis share options. The number of share options granted and exercise prices have been adjusted to reflect the share split of 1:40 in 2001. Broken down by grant year, the number of options held are:

Grant Year	Options held (number)	Conversion Rate	Exercise Price (CHF)	Term life (years)
2002	96,363	1:1	62.0	9
2001	68,280	1:1	70.0	9
	10,000	1:1	62.6	10
2000	81,840	1:1	51.3	9

No options were granted to Non-Executive Directors in 2003 and 2004.

# **Compensation for Former Directors and Executives**

In 2004, we paid a total amount of \$102,000 to two former members of the Board and \$2,541,000 to five former Executives.

### **Executive Compensation Policy**

Our compensation programs are designed to attract, retain and motivate the high-caliber executives, managers and associates who are critical to the success of the Group. Globalization of labor markets for specialists and executives has led to a rapid convergence between US and European principles of compensation and a strong focus on long-term, equity-based forms of programs. Overall, the intention of these programs is to provide compensation opportunities that:

- Are comparable to those provided by a selected group of industry-specific competitors;
- Support a performance-oriented culture that allows high performers to achieve superior rewards; and
- Align executives, management and associates to create sustainable shareholder value.

Total individual compensation at target performance level is aimed at the median of comparable companies of the industries in which we are present. Annual cash and equity incentive awards are based on both overall Group or affiliate company and individual performance. Long-term incentive awards include share options and other forms of equity participation. Executive compensation programs strongly encourage significant levels of share ownership and put a high portion of total compensation at risk, subject to individual and company performance and the appreciation of Novartis shareholder value. In addition, to further strengthen the Company's ownership philosophy, the Board of Directors established in 2003 share ownership guidelines under which designated executives are required to own a multiple of their base salary in Novartis shares.

# **Compensation Program Descriptions**

The total compensation package for each executive consists of the three basic components discussed in more detail below. Target salary and incentive levels are aimed at the median of the peer group, based on available public data and an analysis of external compensation advisors. Actual compensation levels of individuals may in some instances surpass the median of the market, reflecting superior results. The Compensation Committee believes that this position is consistent with the performance of the Group and its evaluation of the external market.

#### Salaries

The 2004 salaries of the Executive Committee members are shown in the "Salary" column of the 2004 Summary Compensation Table on page 137.

# Annual Incentive Awards

Under the terms of the Novartis Annual Incentive Plan, awards are made each year based on the achievement of predetermined Group and individual performance objectives. Below a certain performance threshold, no awards may be granted under the plan.

# Long-Term Incentive Compensation

Long-term incentive compensation, in the form of share options, shares contingent on performance, and restricted shares, comprises a major portion of the total compensation package for executives. In any given year, an executive may be offered share options, performance-contingent shares, and/or restricted shares. Long-term incentives are aimed at the median of the competitive market, with above-average and superior performance resulting in long-term compensation above the targeted amounts. Below a threshold level of performance, no awards may be granted under the plan. Share options are also granted to selected employees.

# Share Options

In 2004, the Board of Directors adopted a modification to the Share Option Plans described below. Under the plan called "Select," participants have the choice to receive their share option award in the form of share options, or restricted shares or in equal parts in share options and restricted shares. An exchange ratio of share options to shares is set by the Board. For 2004, four share options could be exchanged for one share. Shares granted have a restriction period identical to the vesting period of the share options.

# (a) Novartis Share Option Plan

Under the Novartis Share Option Plan, Directors (through 2002), executives and other selected employees of Group companies (collectively, the "Participants") may be granted options on Novartis shares. These options are granted both in recognition of past performance and as an incentive for future contributions by the Participants. They allow the Participants to benefit as the price of the shares increases over time, and so provide a long-term incentive for improvements in our profitability and success. The share options are tradable; therefore they can be used to purchase the underlying Novartis share or they can be sold. If a Participant voluntarily leaves Novartis, share options not yet vested generally forfeit. In 2004, the vesting period for the Novartis Share Option Plan was changed from a two-year vesting period to a three-year vesting period for most countries. Due to pending tax legislation in Switzerland, it was decided not to implement the three-year vesting period in Switzerland. The current view is that the new law will come into force in 2006/2007, at which point the vesting period might be reviewed. The share options under the Novartis Share Option Plan have a term of seven years and an exchange ratio of 1:1.

# (b) Novartis US ADS Incentive Plan for US-based employees

Introduced in 2001, the Novartis US American Depositary Shares (ADS) Incentive Plan grants ADS options to US-based Directors (through 2002), officers and other selected employees, thus replacing a Share Appreciation Rights Plan. The terms and conditions of the US ADS plan are substantially equivalent to the Novartis Share Option Plan. As of 2004, ADS options granted under the plan are transferable to a market maker.

#### Share Plans

We offer to nominated executives a Long-Term Performance Plan, a Leveraged Share Savings Plan and a Restricted Share Plan. These plans are designed to foster long-term commitments by eligible employees to Novartis by aligning their incentives with our performance.

### (a) Long-Term Performance Plan

Under the Long-Term Performance Plan, participants are awarded the right to earn Novartis shares. Actual payouts, if any, are determined with the help of a formula which measures, among other things, our performance using economic value added relative to predetermined strategic plan targets. Additional functional objectives may be considered in the evaluation of performance. If performance is below the threshold level of the predetermined targets, then no shares will be earned. To the extent the performance exceeds the threshold performance level, participants are eligible to receive an increasing amount of Novartis shares, up to the maximum cap. Payout of shares is conditioned on the participant remaining in the employ of a Novartis affiliate at the time of payout.

### (b) Leveraged Share Savings Plan

There are two separate Leveraged Share Savings Plans. Under the first plan, participating executives can choose to receive part or all of their Annual Incentive Award in shares. Shares awarded under this plan are blocked for five years after the grant date. After expiration of the blocking period, the respective shares are matched with an equal number of shares. Under the second plan, employees with a Swiss contract can choose to receive all or part of their annual incentive payout in Novartis shares. After the expiration of a blocking period of three years, the award is matched with half a share for each share held.

Generally, no matching shares will be granted if an employee voluntarily leaves Novartis prior to the expiration of the blocking period.

# (c) Restricted Share Plan

Under the Restricted Share Plan, employees may be granted restricted share awards either as a result of a general grant or as a result of an award based on having met certain performance criteria. Shares granted under this Plan generally have a five-year vesting period. If a participant voluntarily leaves Novartis, unvested shares generally forfeit.

# **Employee Benefits**

Employee benefits offered to executives are designed to be competitive and to provide a safety net against the financial catastrophes that can result from disability or death, and to provide a reasonable level of retirement income based on years of service with Novartis.

# Evaluation of the Executive Committee Members' Performance

The Compensation Committee and the Board of Directors meet without the Chairman and CEO to evaluate his performance, and with the Chairman and CEO to evaluate the performance of other Executive Committee members. The bonuses and long-term incentives for 2003 and the base salaries for 2004 were discussed and approved at the meetings of the Compensation Committee held in January 2004. The decisions on compensation of Executive Committee members were mainly based on individual performance evaluations in which market conditions were also taken into consideration. Similar to 2003, the Compensation Committee considered management's achievement of short and long-term goals, including revenue growth, economic value creation (operating and net income, earnings per share and economic value added) and ongoing efforts to optimize organizational effectiveness and productivity. The Compensation Committee also takes into consideration management's responses to the changes in the global marketplace and the strategic position of the Group. The performance measures were weighted subjectively by each member of the Compensation Committee.

# **Summary**

The Compensation Committee believes that the compensation practices and compensation philosophy of Novartis align executive and shareholder interests. Ongoing adaptation of the programs and practices further allowed the Company to attract, retain and motivate the key talent Novartis needs to continue to compete and provide a strong return to shareholders.

### **Executive Compensation**

In 2004, there were 20 Executive Committee members, Permanent Attendees to the Executive Committee and Business Unit Heads ("Executives"), including those who retired or terminated their employment in 2004. In total, the Executives received \$11,104,000 in salaries and \$3,786,000 in cash bonuses. The number of share options granted was 1,649,650 and the number of shares granted was 833,883. An additional \$1,366,000 was set aside for their pension, retirement and other benefits. Compensation represents all payments made in 2004; however, cash bonuses and long-term compensation are based on 2003 business performance. The following summary compensation table provides details on the 2004 compensation of the Executive Committee members in their respective currencies.

	Annu	al Compensi	sation	Long-Term Compensation				
Name and Principal Position	Currency	Salary	Cash Bonus	Restricted Share Awards (number) <sup>(1)</sup>	Unrestricted Share Awards (number) <sup>(2)</sup>	Share Options (number) <sup>(3)</sup>	All Other Compensation <sup>(4)</sup>	Total <sup>(5)</sup>
Daniel Vasella, M.D. Chairman & CEO	CHF	3,000,000	_	237,891	104,439	533,808	172,649	20,786,304
Urs Bärlocher, J.D.		, ,		<i>,</i>	,	,	,	, ,
Head of Legal & General Affairs .	CHF	791,667	_	14,035	9,792	114,769	154,750	2,566,951
Raymund Breu, Ph.D. Chief Financial Officer	CHF	991,667		19,844	12,403	324,556	158,590	4,605,912
Paul Choffat, J.D. Head of	CIII	991,007	_	19,044	12,405	524,550	156,590	4,003,912
Consumer								
Health Thomas Ebeling	CHF	791,667	577,500	4,309	9,792	176,157	160,440	3,591,274
Head of Pharmaceuticals .	CHF	1,000,000	1,200,000	66,219	15,666	213,524	623,990	8,614,693
Mark C. Fishman, M.D. Head of Biomedical								
Research	USD	850,000	12,425	42,717	13,446	112,932	114,504	4,850,491

### 2004 Summary Compensation Table

(1) The Restricted Share Awards include shares granted under the Leveraged Share Savings Plan, shares granted under the "Select" plan and other restricted share grants.

<sup>(2)</sup> The Unrestricted Share Awards include shares granted under the Long-Term Performance Plan.

(3) The share options granted provide the right to purchase one share per option. Share options granted under the Novartis Share Option Plan have a closing price at grant and an exercise price of CHF 57.45 per share. The options have a cliff-vesting period of two years after the date of grant and will expire on February 3, 2014. The tradable share options have a tax value of CHF 7.46 per option, calculated based on the Black-Scholes Method. Share options have a cliff-vesting period of three years after the date of grant and an exercise price of \$46.09 per share. The options have a cliff-vesting period of three years after the date of grant and will expire on February 3, 2014. The tradable share options have a value of \$11.29 per option, calculated based on the Black-Scholes Method.

<sup>(4)</sup> Amounts include, among others, payments made by Novartis to the Management Pension Fund, a defined-contribution plan.

<sup>(5)</sup> The total compensation amounts have been calculated using the taxable value or Black-Scholes value of the shares and share options granted.

# **Distribution of Share Options Granted to Employees**

Under the Novartis Share Option Plan and the Novartis US ADS Incentive Plan described above, a total number of 14.1 million share options and 2,232,037 shares were granted to 7,626 participants in 2004. Under these plans, 12% of the share options were granted to the Executives.

As of December 31, 2004, a total of 62.7 million share options were outstanding, providing the right to an equal number of shares, which corresponds to 2.3% of the nominal outstanding share capital of Novartis AG.

### Ownership of Novartis Shares and Share Options by the Executives

As of December 31, 2004, the total number of Novartis shares owned by the Executives and persons closely linked to them was 1,685,807. "Persons closely linked to them" are (i) their spouse, (ii) their children below the age of 18, (iii) any legal entities that they own or otherwise control, and (iv) any legal or natural person who is acting as their fiduciary. No Executive owned 1% or more of our outstanding shares. As of December 31, 2004, the individual ownership of Novartis shares of the Executive Committee members (including persons closely linked to them) was as follows:

Beneficial Owner	Number of shares owned directly or indirectly
Daniel Vasella, M.D.	745,899
Urs Bärlocher, J.D.	
Raymund Breu, Ph.D.	221,743
Paul Choffat, J.D.	21,760
Thomas Ebeling	
Mark C. Fishman, M.D.	48,462
Total	1,304,378

The 19 Executives in office as of December 31, 2004, held a total of 6,564,624 Novartis share options. The number of share options and exercise price were adjusted to reflect the share split of 1:40 in 2001. Broken down by grant year since 2000, the numbers of share options held are:

Grant Year	Options held (number) <sup>(1)</sup>	Conversion Rate	Exercise Price (CHF)	Term life (years)
2004	1,649,650	1:1	57.45	10
2003	3,203,537	1:1	49.00	9
2002	1,634,097	1:1	62.00	9
2001	62,740	1:1	70.00	9
2000	4,600	1:1	51.33	9

(1) The number of share options held includes share options granted under the Novartis Share Option Plan and the US ADS Incentive Plan.

### **Benefit Plans**

#### **Swiss Employee Benefit Plans**

# (a) Swiss Pension Fund

The Swiss Pension Fund is a defined-benefit fund that provides retirement benefits and risk insurance (covering death or disability). The Swiss Pension Fund is funded by contributions from Group companies and the insured employees. The Swiss Pension Fund insures remuneration up to a maximum of CHF 220,000 per year. The maximum retirement pension is 60% of the insured remuneration after 40 years of contribution. The table shows the annual pension benefit by base salary and years of service. In

2004, Novartis contributed CHF 18,700 to the Pension Fund in respect of each of the Swiss-based Executive Committee members.

	Years of Service					
Base Salary (CHF)	15	20	25	30	35	40
100,000	17,076	22,764	28,464	34,152	39,840	45,528
140,000	26,076	34,764	43,464	52,152	60,840	69,528
180,000	35,076	46,764	58,464	70,152	81,840	93,528
220,000	44,076	58,764	73,464	88,152	102,840	117,528
over 220,000	44,076	58,764	73,464	88,152	102,840	117,528

### (b) Swiss Management Pension Fund

The Swiss Management Pension Fund is basically a defined-contribution plan and provides retirement benefits and risk insurance (covering death or disability) for components of remuneration not covered by the Swiss Pension Fund. Swiss law provides certain minimum requirements, e.g. return on employee contributions; however, these requirements do not substantially affect the "defined-contribution-character" of the pension plan. Employees exceeding the maximum insurable remuneration of the Swiss Pension Fund are eligible for the Swiss Management Pension Fund. The benefits under the Swiss Management Pension Fund are granted in addition to those of the Swiss Pension Fund. The Swiss Management Pension Fund is funded through contributions by Novartis and the employee.

# **US-Based Employee Pension Plan**

The Pension Plan for US-based employees of Novartis Corporation (Pension Plan) is a funded, tax-qualified, noncontributory defined-benefit pension plan that covers certain employees of Novartis Corporation and its US affiliates, including Dr. Fishman. The Pension Plan provides for different pension formulas, depending on which Novartis company is the employer of a particular employee. The pension formula in which Dr. Fishman participates under the Pension Plan is a pension equity (PEP) formula. Benefits under the PEP formula are based upon an employee's highest average earnings for a five-calendar-year period during the last ten calendar years of service with Novartis and the employee's accumulated PEP credits (expressed as a percentage of final average earnings, and ranging from 2% to 13% for each year of service based on the employee's attained age in a particular year), and are payable after retirement in the form of an annuity or a lump sum. The amount of annual earnings covered by the Pension Plan is generally equal to the employee's base salary and annual bonus. The amount of annual earnings that may be considered in calculating benefits under the Pension Plan is limited by law. For 2004, the annual limitation was \$205,000. Novartis Corporation and its US affiliates also maintain various unfunded supplemental pension plans, each of which provides its respective employees with an amount substantially equal to the difference between the amount that would have been payable under the Pension Plan in the absence of legislation limiting pension benefits and the annual earnings that may be considered in calculating pension benefits under tax-qualified pension plans, and the amount actually payable under the Pension Plan.

#### Personal Loans and Severance Agreements

No loans were granted to the executives during 2004 or were outstanding as of December 31, 2004. During 2004, two executives received \$798,000 as severance.

## 6.C Board Practices

## **Director Independence**

The Board of Directors has promulgated independence criteria for its members. These criteria are appended to the Regulations of the Board and can be found on the Internet at http://www.novartis.com/ investors/en/governance. Pursuant to these criteria, the Board has determined that all of its members, save for Dr. Vasella, Mr. Jetzer and Prof. Datar, are independent and have no material dealings with Novartis AG or other companies of the Novartis Group outside their role as a Director.

Dr. Vasella is the only Executive Director. Mr. Jetzer was a member of the Executive Committee until 1999 and continues to support its Government Relations activities under a consultancy agreement. Prof. Datar rendered professional services to the Group prior to his election to the Board in 2003 and, pursuant to NYSE Rules effective as of November 2004 providing a three-year look-back period on compensation other than Board fees paid by an issuer to its directors, is not considered independent. In 2002, Novartis made a gift to Harvard Business School of \$5 million. This amount established and endowed a professorship in the name of Novartis at Harvard Business School. The Board of Directors concluded that this endowment, which under the rules of the New York Stock Exchange must be reported, does not have any influence on the independence of Mr. William W. George, who became a member of the faculty of Harvard Business School in 2004. Prof. Zinkernagel has been delegated to the Scientific Advisory Board of the Novartis Institute for Tropical Diseases (NITD). He is also a delegate to the Board of Directors of the Genomics Institute of the Novartis Research Foundation (GNF).

No Director is a member of a board of directors of a listed company with which any Novartis Group company conducts a material amount of business.

# **Term of Office**

The specific term of office for a Director is determined by the shareholders at a General Assembly on the occasion of his or her election. The average tenure of our Directors is seven years and their average age is 62 years. In principle, a Director is to retire after 12 years of service or the reaching of 70 years of age. The shareholders may grant an exemption from this rule and reelect a member of the Board of Directors for further terms of office of no more than three years at a time.

#### Chairman and CEO, Vice Chairmen, Lead Director

Dr. Vasella has been elected by the Board as its Chairman and also to serve as Chief Executive Officer of the Group. It is the view of the Board that this dual role ensures effective leadership and excellent communication between the shareholders, the Board and Management. The Board has appointed Prof. Sihler and Mr. Rudloff as its Vice Chairmen.

The Board has appointed Prof. Sihler as Lead Director, whose responsibility it is to ensure an orderly process in evaluating the performance of the Chairman and CEO, and to chair the Board's private sessions (i.e., the meetings of the Non-Executive Directors). In case of a crisis, the Lead Director would assume leadership of the Independent Directors. Prof. Sihler is a member of all of the Committees of the Board.

#### Role and Functioning of the Board

The Board holds the ultimate decision-making authority of Novartis AG for all matters except those reserved by law to the shareholders.

The agenda for Board meetings is set by the Chairman. Any Board Member may request that an item be included on the agenda. Board Members are provided, in advance of Board meetings, with adequate materials to prepare for the items on the agenda. Decisions are taken by the Board as a whole, with the support of its four Committees described below (Chairman's Committee, Compensation Committee, Audit and Compliance Committee and Corporate Governance Committee).

The primary functions of the Board are:

- Provide the strategic direction of Novartis.
- Determination of the organizational structure and the manner of governance of the company.
- Overall supervision of the business operations.
- Approval of major acquisitions or divestments.
- Structuring the accounting system, setting financial targets and financial planning.
- Appointing and dismissing members of the Executive Committee and other key executives.
- Promulgation of fundamental corporate policies, in particular on financial matters, corporate governance and citizenship, personnel or environmental matters; and overseeing compliance therewith.
- Preparation of the matters to be presented at the General Meeting, including the Novartis AG financial statements and the Group's consolidated financial statements.

The Board has not concluded any contracts with third parties for the management of the Company but has delegated to the Executive Committee the coordination of day-to-day business operations of Group companies. The Executive Committee is headed by the Chief Executive Officer. The internal organizational structure and the definition of the areas of responsibility of the Board and the Executive Committee are set forth in the Board Regulations.

The Board recognizes the importance of being fully informed on material matters involving the Group and ensures that it has sufficient information to make appropriate decisions through several means:

- By invitation, members of management attend Board meetings to report on areas of the business within their responsibility.
- Board Committees, in particular the Audit and Compliance Committee, regularly meet with management and outside consultants, including the Group's external auditors, to review the business, better understand all laws and policies impacting the Group and support the management in meeting the requirements and expectations of stakeholders.
- Informal teleconferences between Directors and the Chairman and CEO, or the Lead Director, as well as regular distribution of important information to the Directors.

Once yearly, the Board reviews the performance of the Chairman and CEO and approves his business objectives for the following year. The Board of Directors also performs a self-evaluation once a year.

During 2004, the Board met 11 times (including one training session). Detailed information on each Director's attendance at full Board and Board Committee meetings is provided in the following table.

#### Attendance

Detailed information on attendance at full Board and Board Committee meetings is as follows:

	Full Board	Chairman's Committee	Compensation Committee	Audit and Compliance Committee	Corporate Governance Committee
Number of meetings in 2004	11	9	5	8	2
Daniel Vasella, M.D.	$11^{(1)}$	9(1)			
Helmut Sihler, J.D., Ph.D	11	9	5(1)	8(1)	2
Hans-Joerg Rudloff	10	9	5	4(3)	2
Dr. h.c. Birgit Breuel	10			8	
Peter Burckhardt, M.D.	11				
Srikant Datar, Ph.D.	11				
Walter G. Frehner <sup>(2)</sup>	3			3	
William W. George	11	9	5		$2^{(1)}$
Alexandre F. Jetzer	11				
Pierre Landolt	10				
Ulrich Lehner, Ph.D	9	4 <sup>(3)</sup>		8	
Heini Lippuner <sup>(2)</sup>	3	3			
DrIng. Wendelin Wiedeking	7				
Rolf M. Zinkernagel, M.D.	11				2

(1) Chair.

<sup>(2)</sup> Retired as of February 24, 2004.

<sup>(3)</sup> From February 24, 2004.

#### **Role and Functioning of the Board Committees**

Each Board Committee has a written Charter outlining its duties and responsibilities and a chair elected by the Board. The Board Committees meet regularly and consider meeting agendas determined by the Chair. Board Committee members are provided, in advance of meetings, with adequate materials to prepare for the items on the agenda.

#### The Chairman's Committee

The Chairman's Committee consists of the Chairman and Chief Executive Officer, the two Vice Chairmen, one of whom is the Lead Director, and such other members as are elected by the Board from time to time. The Chairman's Committee reviews selected matters falling within the authority of the Board before the latter makes decisions on such matters and, in urgent cases, can take preliminary and necessary actions on behalf of the Board. The Chairman's Committee also interfaces with the Executive Committee, specifically deciding on financial investments and other matters delegated to the Committee by the Board of Directors.

## The Compensation Committee

The Compensation Committee is composed of three independent Directors. The Compensation Committee reviews the compensation policies and programs of the Group, including share option programs and other incentive-based compensation, before the full Board makes final decisions. It is responsible for reviewing and approving the compensation paid to members of the Executive Committee and other selected key executives, and for reviewing the performance of the Chairman and Chief Executive Officer. The Compensation Committee seeks outside expert advice from time to time to support its decisions and recommendations.

## The Audit and Compliance Committee

The Audit and Compliance Committee is composed of four members. The Board has determined that all the members of the Committee are independent, as defined by the rules of the New York Stock Exchange as well as by the independence criteria of Novartis, and that its Chair, Prof. Sihler, is adequately qualified in financial management matters. The Audit and Compliance Committee has determined that Prof. Lehner, possesses the required accounting and financial management expertise required under the rules of the SEC. Therefore the Board of Directors has appointed him as the Audit and Compliance Committee's Financial Expert. The Board has also reassured itself that other members of the Committee have sufficient experience and ability in finance and matters of compliance to enable them to adequately discharge their responsibilities.

The Committee's main duties are:

- Evaluate and select the external auditors to be nominated for election at the Annual General Assembly.
- Review the terms of engagement of the external auditors and the scope of the external audit.
- Discuss with the external auditors the results of their audits.
- Review the scope of internal auditing and the adequacy of the organizational structure and qualifications of the internal auditing staff.
- Review with external auditors, internal auditors and the financial and accounting management of Novartis whether the accounting policies and financial controls are appropriate, adequate and effective.
- Meet with management and the external auditors to review the financial statements and Annual Report.
- Review internal control processes and procedures, including those for the management of business risk.
- Review all relationships between Group companies and external auditors.
- Review the processes and procedures for ensuring compliance with laws and internal regulations (such as the Novartis Code of Conduct).
- Oversee Novartis' commitments as a subscriber to the UN's Global Compact initiative.

### The Corporate Governance Committee

The Corporate Governance Committee is composed of four independent Directors. The Corporate Governance Committee develops corporate governance principles and recommends these to the Board for approval. Its duties include the regular review of the Articles of Incorporation with a view to reinforcing shareholder rights, and of the composition and size of the Board and its committees. The Corporate Governance Committee conducts an annual evaluation of the Board as a whole and gives guidance to the Directors on how to avoid potential conflicts of interest.

### Meetings of the Non-Executive Directors

The non-executive independent directors held 2 private sessions chaired by the Lead Director, Prof. Sihler.

#### **Change of Control and Defense Measures**

The Swiss Stock Exchange Act provides that whoever acquires more than  $33\frac{1}{3}\%$  of the equity securities of a company shall be required to make a bid for all listed equity securities of that company. In its articles of association a company may increase this threshold to 49% (opting up) or, under certain circumstances, waive the threshold (opting out). Novartis has not adopted any such measures in deviation from the rules applicable to it under the Swiss Stock Exchange Act.

The employment agreements with four members of senior Management contain change-of-control provisions whereby their normal contractual severance of 36 months is extended by 24 months during the 12 months following a change of control as defined in those agreements. One executive has a provision whereby the normal contractual severance of 12 months is extended by 12 months during the 12 months following a change of control.

## **Documentation**

The following documents describe the Corporate Governance standards applied by Novartis:

- Articles of Incorporation
- Regulations of the Board and Committee Charters, including the independence criteria for Board and Audit and Compliance Committee members

These documents can be ordered from the Corporate Secretary, Ingrid Duplain, J.D., Novartis International AG, Lichtrasse 35, CH-4056 Basel, Switzerland. They also are available on the Novartis website: http://www.novartis.com/investors/en/governance.shtml.

# **6.D** Employees

The table below sets forth the breakdown of the total year-end number of our full time equivalent employees by main category of activity and geographic area for the past three years.

For the year ended December 31, 2004 (full time equivalents)	Research & Development	Production & Supply	Marketing & Sales	General & Administration	Total
USA	4,333	5,208	9,486	1,875	20,902
Canada and Latin America	427	2,940	4,828	1,089	9,284
Europe	7,351	12,477	13,429	4,972	38,229
Africa/Asia/Australia	1,113	2,483	8,242	1,139	12,977
Total	13,224	23,108	35,985	9,075	81,392

For the year ended December 31, 2003 (full time equivalents)	Research & Development	Production & Supply	Marketing & Sales	General & Administration	Total
USA	3,463	5,013	9,292	2,066	19,834
Canada and Latin America	302	2,937	4,620	915	8,774
Europe	6,904	12,404	13,161	5,041	37,510
Africa/Asia/Australia	905	2,307	7,943	1,268	12,423
Total	11,574	22,661	35,016	9,290	78,541

For the year ended December 31, 2002 (full time equivalents)	Research & Development	Production & Supply	Marketing & Sales	General & Administration	Total
USA	3,214	5,097	9,062	1,971	19,344
Canada and Latin America	297	3,667	4,671	349	8,984
Europe	6,320	10,467	11,487	4,321	32,595
Africa/Asia/Australia	821	2,906	7,873	354	11,954
Total	10,652	22,137	33,093	6,995	72,877

A relatively small number of our employees are represented by unions. We have not experienced any material work stoppages in recent years, and we consider our employee relations to be good.

## 6.E Share Ownership

The aggregate amount of our shares owned by current non-executive Directors and Executives (including persons closely linked to them) as of December 31, 2004 was 2,091,422 shares, which amount is less than 1% of our outstanding shares. No individual non-executive Director or Executive owned 1% or more of our outstanding shares. However, our Director Pierre Landolt is also the Chairman of the Board of Directors of Emasan AG. See "Item 7. Major Shareholders and Related Party Transactions-7.A Major Shareholders."

The aggregate amount of Novartis share and ADS options, including other information regarding the options, held by current Directors and the Executives as of December 31, 2004 is set forth below:

Title of Options	Amount of shares called for by the options	Exercise Price <sup>(1)</sup> (CHF)	Purchase Price (if any)	Expiration Date	Total number of options held
Novas07 Options	1	42.50	0	January 15, 2007	30,880
Novas08 Options	1	68.35	0	January 16, 2008	31,080
Novas09 Options	1	51.33	0	March 10, 2009	97,480
Novas10 Options	1	70.00	0	March 7, 2010	79,760
Novas11 Options	1	62.00	0	March 7, 2011	1,311,203
Novas12 Options	1	48.86	0	February 3, 2012	2,822,805
Novas14 Options	1	57.45	0	February 3, 2014	1,470,878
Total Novartis Share Options					5,844,086
Novartis ADS Options					
Cycle V	1	\$41.97	0	March 7, 2011	54,980
Novartis ADS Options					
Cycle VI	1	\$37.28	0	March 7, 2012	495,887
Novartis ADS Options					
Cycle VII	1	\$36.31	0	February 4, 2013	433,311
Novartis ADS Options					
Cycle VIII	1	\$46.09	0	February 3, 2014	178,772
Novartis ADS Options					
Others	1	\$37.86	0	October 26, 2011	10,000
Total Novartis ADS Options					1,172,950

<sup>(1)</sup> Exercise price indicated is per share.

#### **Novartis Employee Ownership Plans**

Pursuant to the prior Novartis Employee Ownership Plan, which was approved by the Board of Directors in 1998, all employees of our Swiss affiliates were entitled to purchase 120 shares, at a predetermined discount price, after each full year of service. In 2001, the price was set at CHF 12.50 per share. 80 of the shares were freely disposable, and 40 of the shares were required to be deposited with us until the person concerned leaves the employment, or retires from, the relevant Swiss affiliate. These employees were then required to immediately buy the shares to which they became entitled. During 2002 and 2001, an aggregate of 406,448 and 862,720 shares, respectively, were acquired by these employees under this plan.

In January 2002 a Novartis Employee Ownership Plan was introduced for all employees of our Swiss affiliates, replacing the prior plan. These employees receive an annual incentive bonus delivered in Novartis shares at a fixed date at the then valid fair market value of the shares. This plan allows these employees to choose to immediately sell either all or half of the shares received, or to keep all the shares for a three year vesting period, at which time we will give the employee one additional free share for every two shares retained and deposited by the employee under this plan. In March 2004, our Swiss employees received an aggregate of 3,080,673 shares under this plan.

Beginning January 2002, two share ownership plans were introduced for employees of our UK affiliates. The first is the Novartis UK Share Ownership Plan, a UK Inland Revenue-approved plan set up under a Trust. For every two shares purchased, employees will receive one share free. However, the employee would forfeit the matching share and any tax relief received if the employee were to leave the employ of his or her UK employer within 3 years of the award. If the shares are held in the plan for 5 years or more then the employee will not be liable for any form of tax on either the shares they purchased or the free matching shares. The employee's maximum annual investment under this plan is GBP 1,500.

Under the second UK plan, the Novartis UK Incentive Conversion Plan, employees can invest their net incentive bonus, which is the maximum allowable payment to the Novartis UK Share Ownership Plan. For every two shares purchased the employee will receive one free share. But the employee would forfeit the free share if the employee leaves the employ of his or her UK employer within 3 years of the award.

# Item 7. Major Shareholders and Related Party Transactions

## 7.A Major Shareholders

Based on our share register, we believe that we are not directly or indirectly owned or controlled by another corporation or government, and that there are no arrangements that may result in a change of control.

As of December 31, 2004, our registered share capital was CHF 1,388,605,000, divided into 2,777,210,000 shares with a nominal value of CHF 0.50 each. Based on our share register, it appears that approximately 58% of our registered shares are held in Switzerland, and approximately 30% of our shares which are registered by name are held in the United States. However, since certain of our shares are held by brokers or other nominees, and because 24% of our shares are not registered in anyone's name, the above numbers are not representative of the actual number of beneficial owners of our shares located in the US or in Switzerland.

As of December 31, 2004 no person or entity was the owner of more than 5% of our shares, whether or not the voting rights of such shares were exercisable. Our largest registered shareholders are Emasan AG (3.2%) and the Novartis Foundation for Employee Participation (3.1%). In 2003, these shareholders held 3.1% and 3.3% respectively. Both shareholders are entered in the share register with voting rights for their entire shareholdings.

The largest registered nominee shareholder with voting rights is JPMorgan Chase Bank, N.A. (7.6%), which entered into a nominee agreement with us and disclosed the names, addresses and number of shares of the beneficial owners for whose account it holds the shares. JPMorgan Chase Bank, N.A. also holds an additional 7.1% of our shares in its capacity as the Depositary for our ADSs. The second largest nominee shareholder is Nortrust Nominees (2.3%). Based on a nominee agreement with us and the regular disclosure of the beneficial owners for whom it holds the shares, this shareholder has voting rights for its entire shareholding No other nominee shareholders nor any beneficial owner known to us holds more than 2% of our shares.

#### Shares

We have one class of shares. As of December 31, 2004, a total of 2,777,210,000 shares were issued, with a nominal value of CHF 0.50 each. The shares are fully paid-in and non-assessable.

We may issue certificates representing several shares. Shareholders may exchange these certificates at any time for certificates representing smaller numbers of shares, or for individual share certificates. If the owner of the shares consents, we may renounce the printing and delivery of share certificates.

#### **Capital Structure**

As of December 31, 2004, our share capital was CHF 1,388,605,000, made up of 2,777,210,000 fully paid-in registered shares, each with the nominal value of CHF 0.50. On February 24, 2004, our shareholders approved a reduction of our share capital by CHF 12,130,000. We have submitted a new proposal to our shareholders, to be voted upon at their next Shareholders Meeting on March 1, 2005, for a further reduction of our share capital by CHF 19,019,500.

As of December 31, 2004, we held 437,718,075 shares in our treasury, calculated in accordance with US GAAP. When calculated in accordance with IFRS, the number of treasury shares was 350,399,924. These numbers differ because of varying rules regarding whether shares held by certain foundations, which are independent from Novartis under Swiss company law, must be consolidated with shares held by the Group as treasury shares. US GAAP requires that we consolidate shares held by the employee share participation foundation. This is not required under IFRS.

Since 2001 we have made available to US investors a direct ADS purchase and dividend reinvestment program through our depositary bank, JPMorgan Chase Bank, N.A. Since September 2004, we have also offered a Direct Share Purchase Program to investors residing in Switzerland, Liechtenstein, France and the UK. See "Item 5. Operating and Financial Review and Prospects—5.B. Liquidity and Capital Resources."

#### **American Depositary Shares**

We incorporate by reference the disclosure regarding our ADS program included in the registration statement on Form 20-F/A (File No. I-15024), as filed with the Commission on May 9, 2000, in the section entitled "Part II—Item 14. Description of Securities to be Registered—American Depositary Receipts."

On May 3, 2001, we filed an Amendment No. 2 to the Amended and Restated Deposit Agreement, dated as of May 7, 2001, pursuant to the Registration Statement on Form F-6 (File No. 333-13446). The Amendment No. 2 changed the ADS-to-share ratio from 40-to-1 to 1-to-1.

On January 31, 2002, we filed a Restricted Issuance Agreement dated as of January 11, 2002, supplementing Amendment No. 2 to the Amended and Restated Deposit Agreement dated as of May 3, 2001, as an exhibit to the Registration Statement on Form F-3 (File No. 333-81862). The Restricted Issuance Agreement supplemented the Deposit Agreement to permit the deposit of restricted ADSs into a parallel facility to the ADR facility established in the Deposit Agreement.

On October 27, 2004, we entered into a letter agreement with JPMorgan Chase Bank by which the 5% limitation set forth in the third paragraph of Paragraph 13 of the form of ADR set forth in Exhibit A to the Amended and Restated Deposit Agreement was increased to 8%.

### 7.B Related Party Transactions

We have formed certain foundations for the purpose of advancing employee welfare, employee share participation, research and charitable contributions. The charitable foundations foster health care and social development in rural countries. The foundations are autonomous, and their boards are responsible for administering the foundations in accordance with the foundations' purpose and applicable law.

The employee share participation foundation has not been included in our consolidated financial statements prepared under IFRS, as SIC Interpretation No. 12, as issued by the Standing Interpretations Committee exempts post-employment and equity compensation plans from its scope. The total assets of this foundation, as of December 31, 2004, included 87.3 million of our shares with a market value of approximately \$4.4 billion. As of December 31, 2003, the assets included 93.3 million of our shares with a market value of approximately \$4.2 billion. As of December 31, 2002, the assets included 95.1 million of our shares with a fair market value of \$3.4 billion. This foundation has been consolidated with our

financial statements under US GAAP, and is included as a reconciling item in the US GAAP reconciliation.

In 2004 we granted short-term loans totaling \$713 million to the employee welfare and other foundations and received short-term loans totaling \$16 million from them. In 2003 we granted short-term loans totaling \$651 million to the employee welfare and other foundations and received short-term loans totaling \$8 million from them. In 2002, we granted short-term loans totaling \$623 million to these foundations and received short-term loans totaling \$2 million from them.

#### 7.C Interests of Experts and Counsel

Not applicable.

#### Item 8. Financial Information

#### 8.A Consolidated Statements and Other Financial Information

8.A.1 See Item 18.

8.A.2 See Item 18.

8.A.3 See Report of Independent Auditors, page F-2.

8.A.4 We have complied with this requirement.

8.A.5 Not applicable.

**8.A.6** Not applicable.

#### 8.A.7 Legal proceedings.

*Litigation*: A number of our affiliates are the subject of litigation arising out of the normal conduct of their business. As a result, claims could be made against them which, in whole or in part, might not be covered by insurance. In our opinion, however, the outcome of these actions will not materially affect our financial condition but could be material to our results of operations in a given period. In the interest of transparency we are providing information on the following civil cases:

- Average Wholesale Price Litigation: Claims have been brought against various US pharmaceutical companies, including Novartis affiliates, alleging that they have fraudulently overstated the Average Wholesale Price (AWP) and "best price," which are used by the US government to calculate, respectively, Medicare and Medicaid reimbursements. Novartis affiliates have been named in a number of these cases. Discovery is in process against certain defendants in these cases, but not yet against us. Novartis affiliates have also voluntarily participated in an ongoing Congressional inquiry on the subject of AWP and pharmaceutical pricing.
- Canadian Importation Cases: Novartis affiliates, along with various other pharmaceutical companies, are parties to suits alleging a conspiracy among pharmaceutical companies to keep prices of pharmaceuticals in the US artificially high by blocking imports of Canadian drugs to US consumers. Pretrial motion practice is underway in these cases.
- Chiron: We own approximately 42.5% of the shares of Chiron Corporation. Chiron and its officers and directors are currently the subject of a number of lawsuits and government investigations which include allegations of, among other things, breaches of the securities laws and of fiduciary duties, arising out of Chiron's inability to deliver its Fluvirin<sup>®</sup> influenza vaccine to the US market for the 2004/05 flu season. Novartis AG has been named as a defendant in three of these cases. All of these cases are in the earliest stages.

- **HRT Litigation:** A Novartis affiliate is a defendant, along with various other pharmaceutical companies, in approximately 60 cases brought by people claiming to have been injured by hormone replacement therapy products. Discovery is underway in these cases.
- **Pharmaceutical Antitrust Litigation:** A Novartis affiliate, along with numerous other prescription drug manufacturers, is a co-defendant in various actions brought by certain US retail pharmacies alleging antitrust and pricing violations. Pretrial motion practice is underway.
- **PPA:** Novartis affiliates are parties to approximately 250 lawsuits in the US brought by people claiming to have been injured by products containing phenylpropanolamine (PPA) sold by certain of those affiliates. These cases are in various stages of litigation with Novartis having achieved victories in the first three lawsuits to have gone to trial. However, other trials are currently ongoing, and more trials are expected to follow. There can be no guarantee that our initial successes will be repeated or sustained in the event of an appeal.
- SMON: (Subacute Myelo Optico Neuropathy): In 1996 an affiliate of Ciba-Geigy, one of our predecessor companies, together with two other pharmaceutical companies, settled certain product liability issues related to sales of its product *Clioquinol* in Japan. Under the settlement, one of our affiliates is required to pay certain future health care costs of the claimants.
- **Terazosin:** One of our Sandoz affiliates is a defendant in a number of lawsuits in the US claiming injuries and damages allegedly arising out of violation of antitrust laws in the settlement, by the affiliate and Abbott Pharmaceuticals, of a contentious patent litigation involving Abbott's Hytrin<sup>®</sup> and the Sandoz generic equivalent product. Our affiliate has a judgment sharing agreement with Abbott that caps its liability. In addition, in one of the proceedings, we were successful in overturning on appeal trial court decisions that the settlement of the litigation was *per se* unlawful and certifying a plaintiff's class. The case has been remanded to the trial court for further proceedings.

We believe that our affiliates have meritorious defenses in these cases, and they are vigorously defending each of them.

We maintain property damage, business interruption, product liability and other insurance policies with third parties, covering claims on a worldwide basis. We believe that our insurance coverage and provisions are reasonable and prudent in light of our business and the risks to which we are subject. However, events may occur which in whole or in part, might not be covered by third party insurance or the provisions that we have put in place. This is particularly true with respect to product liability claims where other pharmaceutical companies have faced large losses, making third party insurance coverage increasingly difficult to obtain. As a result, while no such losses are presently expected, there can be no guarantee that we will not also face a loss which far exceeds available insurance or provisions.

Intellectual Property Litigation: A number of our affiliates are parties to litigation regarding intellectual property rights. See "Item 4. Information on the Company—4.B Business Overview— Pharmaceuticals—Intellectual Property"; "Item 4. Information on the Company—4.B Business Overview—Sandoz—Intellectual Property"; and "Item 4. Information on the Company—4.B Business Overview—CIBA Vision—Intellectual Property."

*Investigations:* From time to time, our affiliates may be the subject of government investigations arising out of the normal conduct of their business. Consistent with the Novartis Code of Conduct and policies regarding compliance with law, it is our policy to cooperate with such investigations.

• US enteral pump market: A Novartis Medical Nutrition affiliate in the US is a subject of an investigation by the US Department of Justice regarding marketing and pricing practices in the US enteral pump market, including whether certain federal criminal statutes have been violated. Novartis is in the process of negotiating a possible settlement of that investigation.

• UK generics: One of our UK Sandoz affiliates, along with other generic drug companies, is a subject of an investigation by the UK Serious Fraud Office ("SFO") to determine whether its marketing practices during the period prior to its acquisition by Novartis violated criminal or competition laws. We are cooperating with the SFO's investigation.

#### 8.A.8. Dividend policy

Subject to the dividend policy described below, our Board of Directors expects to recommend the payment of a dividend in respect of each financial year. If approved by our shareholders at the relevant annual Shareholders' Meeting, the dividends will be payable immediately following such approval. Any shareholder who purchased our shares on or before the second trading day after the shareholders' meeting shall be deemed to be entitled to receive the dividends and, in bonus issues, new shares, and to exercise shareholders' preemption rights to participate in issues of securities. Dividends are reflected in our financial statements in the year in which they are approved by our shareholders.

Our Board's stated policy is that, over the long term, the size of the dividend should be geared to growth in our after-tax earnings. All future dividends paid by us will depend upon our financial condition at the time, the results of our operations and other factors.

The Board will propose a dividend of CHF 1.05 per share to the shareholders for approval at the Annual General Meeting to be held on March 1, 2005. Because we pay dividends in Swiss francs, exchange rate fluctuations will affect the US dollar amounts received by holders of ADSs. For a summary of dividends we paid in the past five years, see "Item 3. Key Information—3.A Selected Financial Data—Cash Dividends per Share."

## 8.B Significant Changes

On February 24, 2004, our shareholders approved a reduction of our share capital by CHF 12,130,000. Our share capital is now CHF 1,388,605,000 and is divided into 2,777,210,000 shares with a nominal value of CHF 0.50 each.

We will submit a new proposal to our shareholders, to be voted upon at their next Annual General Meeting on March 1, 2005, for a further reduction of our share capital by CHF 19,019,500, as a means of fully retiring those shares acquired as a result of the share repurchase programs. In addition, we will propose to our shareholders, to be voted on at the March 1, 2005 Annual General Meeting, to initiate a fifth share repurchase program of up to CHF 4 billion, with the aim of canceling the shares bought back.

## Item 9. The Offer and Listing

## 9.A Listing Details

Our shares are listed in Switzerland on the SWX Swiss Exchange ("SWX"). The principal trading market for our shares is the virt-x, a virtual exchange created by, among others, the SWX. Prior to the creation of virt-x in June 2001, our shares were traded on the SWX. Since 1996, our shares were quoted on London's SEAQ International and now on the International Retail Service of the London Stock Exchange.

American Depositary Shares (ADSs), each representing one share, have been available in the US through an American Depositary Receipts (ADR) program since December 1996. This program was established pursuant to a Deposit Agreement which we entered into with JPMorgan Chase Bank N.A. as Depositary (the "Deposit Agreement"). Our ADSs have been listed on the NYSE since May 2000, and are traded under the symbol "NVS."

The table below sets forth, for the periods indicated, the high and low closing sales prices for our shares traded in Switzerland and for ADSs traded in US. The data below regarding our shares reflects price and volume information for trades completed by members of the virt-x (or the SWX, as applicable) during the day as well as for inter-dealer trades completed off the virt-x (or the SWX, as applicable) and certain inter-dealer trades completed during trading on the previous business day. The data below has been adjusted to reflect the 40-for-1 share split and diminution in nominal share value from CHF 20 to CHF 0.50 and the ADS-share ratio change from 40-for-1 to 1-for-1 effective May 7, 2001. Each ADS now represents one share.

The following share data was taken from virt-x and SWX; the ADS data was taken from Bloomberg:

	Shares		ADSs	
	High	Low	High	Low
	(CHF pe	er share)	(\$ per ADS)	
Annual information for the past five years				
2004	59.95	52.10	50.62	41.30
2003	56.15	46.05	45.89	35.54
2002	69.10	50.00	43.83	34.10
2001	74.15	54.95	45.00	32.98
$2000^{(1)}$	73.90	49.72	44.75	35.12
Quarterly information for the past two years				
2004				
First Quarter	58.50	52.10	47.64	41.30
Second Quarter	58.60	54.50	46.80	41.86
Third Quarter	59.95	53.25	47.68	43.30
Fourth Quarter	59.35	54.60	50.62	45.49
2003				
First Quarter	54.80	46.05	39.02	34.54
Second Quarter	55.30	49.75	41.85	36.71
Third Quarter	55.70	51.05	40.22	36.97
Fourth Quarter	56.15	50.55	45.89	37.24
Monthly information for most recent six months				
August 2004	58.50	56.50	46.45	44.96
September 2004	59.95	58.20	47.68	46.32
October 2004	59.35	56.35	48.01	45.49
November 2004	59.35	54.60	50.46	47.69
December 2004	57.30	55.60	50.62	48.55
January 2005 (through January 25)	58.00	55.80	50.27	47.51

<sup>(1)</sup> Share prices have been revised for 2000, to reflect the share split which occurred on May 7, 2001 resulting in a share: ADS ratio change from 40:1 to 1:1.

Fluctuations in the exchange rate between the Swiss franc and the US dollar will affect any comparisons of Swiss share prices and US ADS prices.

The average daily volumes traded on the virt-x for the years 2004, 2003 and 2002 were 8,108,758, 9,927,022 and 9,744,732 respectively. These numbers are based on total annual turnover statistics supplied by the virt-x via the Swiss Market Feed, which supplies such data to subscribers and to other information providers. The average daily volumes traded on the NYSE for the years 2004, 2003 and 2002 were 657,255, 575,885 and 468,792, respectively.

A 2-for-1 share split for the ADSs was effected on May 11, 2000. A 40-for-1 share split of the shares was effected on May 7, 2001 simultaneously with an ADS-to-share ratio change from 40-for -1 to 1-for-1.

The Depositary has informed us that as of January 25, 2005, there were 198,331,660 ADSs outstanding, each representing one Novartis share (approximately 7.14% of all outstanding and treasury shares). On January 25, 2005, the closing sales price per share on the virt-x was CHF 57.60 and per ADS on the NYSE was \$ 48.25.

# 9.B Plan of Distribution

Not applicable.

# 9.C Market

See "9.A Listing Details."

# 9.D Selling Shareholders

Not applicable.

# 9.E Dilution

Not applicable.

## 9.F Expenses of the Issue

Not applicable.

### Item 10. Additional Information

## 10.A Share capital

Not applicable.

## 10.B Memorandum and Articles of Association

The following is a summary of certain provisions of our Articles of Incorporation (the "Articles"), and of the Swiss Code of Obligations (the "Swiss Code"). This is not a summary of all the significant provisions of the Articles or of Swiss law. This summary is qualified in its entirety by reference to the Articles, which are an exhibit to this Form 20-F, and to Swiss law.

## **10.B.1** Company Purpose

Novartis AG is registered in the commercial register of the Canton of Basel-Stadt, Switzerland under number CH-270.3.002.061-2. Our business purpose, as stated in Article 2 of the Articles, is to hold interests in enterprises in the area of health care or nutrition. We may also hold interests in enterprises in the areas of biology, chemistry, physics, information technology or related areas. We may acquire, mortgage, liquidate or sell real estate and intellectual property rights in Switzerland or abroad.

#### **10.B.2** Directors

(a) According to our Regulations of the Board (the "Board Regulations"), our Directors may not participate in deliberations or resolutions on matters which affect, or reasonably might affect, the Director's interests, or the interests of a person close to the Director. In addition, while the Swiss Code does not have a specific provision on conflicts of interests, the Swiss Code does require directors and members of senior management to safeguard the interests of the corporation and, in this connection, imposes a duty of care and a duty of loyalty on such persons. This rule is generally interpreted to mean that directors and members of senior management are disqualified from participating in decisions which affect them personally. Directors and officers are personally liable to the corporation for any breach of these provisions.

(b) Directors may not vote that they receive compensation unless at least a majority of the Directors are present.

(c) The Articles and the Board Regulations contain no specific provision permitting or prohibiting Directors from borrowing from us. The Articles do permit the Board of Directors to pass resolutions with respect to all matters, such as this one, which are not reserved to the authority of the General Meeting of Shareholders by law or by the Articles. In addition, Swiss law contains a provision under which a Director, or any other persons associated with a Director, must refund to the corporation any payments made to them by the corporation, other than payments made at arm's length. Under the provisions of the US Sarbanes-Oxley Act, enacted in July 2002, no new loans may be given to directors or executive officers. Prior to the Act, loans had been granted to two executive officers. These loans have been repaid in full.

(d) Directors must retire effective as of the next Ordinary General Meeting of shareholders after they have completed their twelfth year on the Board, or when they reach age 71, whichever comes first. The General Meeting may, under special circumstances, grant an exception from this rule and may elect a Director for further terms of office of no more than three years

(e) Under the Articles and Swiss law, each of our Directors must also be a shareholder. Ownership of one share is sufficient to satisfy this requirement.

#### **10.B.3** Shareholder Rights

Because we have only one class of registered shares, the following information applies to all shareholders.

(a) Swiss law requires that at least 5% of our annual net profits be retained as general reserves, so long as these reserves amount to less than 20% of our registered share capital. The law and the Articles permit us to accrue additional reserves.

Under Swiss law, we may only pay dividends if we have sufficient distributable retained earnings from previous fiscal years, or if our reserves are sufficient to allow distribution of a dividend. In either event, under Swiss law, while the Board of Directors may propose that a dividend be paid, we may only pay dividends upon shareholder approval at a shareholders' meeting. Our auditors must confirm that the dividend proposal of the Board conforms with the Swiss Code of Obligations and the Articles. Our Board of Directors intends to propose a dividend once each year. See "Item 3. Key Information—3.A. Selected Financial Data—Cash Dividends per Share."

Dividends are usually due and payable immediately after the shareholders have passed a resolution approving the payment. Dividends which have not been claimed within five years after the due date fall back to us, and are allocated to our general reserves. For information about deduction of the withholding tax from dividend payments, see "Item 10. Additional Information—10.E Taxation."

(b) Each share is entitled to one vote at the shareholders' meeting. A shareholder may exercise its right to vote its shares only after the shareholder has been recorded in the share register as being entitled to such rights at least 20 days in advance. In order to do so, the shareholder must file a share registration

form with us at least 20 days in advance, setting forth the shareholder's name, address and citizenship (or, in the case of a legal entity, its registered office). If the shareholder has not filed the form at least 20 days in advance, then the shareholder may not vote at, or participate in, shareholders' meetings.

To vote its shares, the shareholder must also explicitly declare that it has acquired the shares in its own name and for its own account. If the shareholder refuses to make such a declaration, the shares may not be voted unless the Board of Directors grants voting rights to a nominee for those shares. The Board of Directors may grant such nominees the right to vote up to 0.5% of the total number of registered shares.

No shareholder or group of shareholders may vote more than 2% of the registered shares. If a shareholder holds more than 2% of Novartis' shares, that shareholder will be entitled to register the excess shares, but not to cast votes based upon them.

For purposes of the 2% rule for shareholders and the 0.5% rule for nominees, groups of companies and groups of shareholders acting in concert are considered to be one shareholder. The Board of Directors may, on a case by case basis, allow exceptions from both the 2% rule for shareholders and the 0.5% rule for nominees. The Board may delegate this power. To date, such a request has never been denied. Finally, the shareholders may cancel the voting restrictions upon a resolution carrying a two-thirds majority of the vote at a shareholders meeting.

After hearing the registered shareholder or nominee, the Board of Directors may cancel, with retroactive effect as of the date of registration, the registration of shareholders if the registration was effected based on false information.

Shareholders' resolutions generally require the approval of a majority of the votes present at a shareholders' meeting. As a result, abstentions have the effect of votes against the resolution. Shareholders' resolutions requiring a vote by such "absolute majority" include (1) amendments to the Articles; (2) elections of directors and statutory auditors; (3) approval of the annual report and the annual accounts; (4) setting the annual dividend; (5) decisions to discharge directors and management from liability for matters disclosed to the shareholders' meeting; and (6) the ordering of an independent investigation into specific matters proposed to the shareholders' meeting.

According to the Articles and Swiss law, the following types of shareholders' resolutions require the approval of a "supermajority" of at least two-thirds of the votes present at a shareholders' meeting: (1) an alteration of our corporate purpose; (2) the creation of shares with increased voting powers; (3) an implementation of restrictions on the transfer of registered shares and the removal of such restrictions; (4) an authorized or conditional increase of the share capital; (5) an increase of the share capital by conversion of equity, by contribution in kind, or for the purpose of an acquisition of property or the grant of special rights; (6) a restriction or an elimination of shareholders' preemptive rights; (7) a change of our domicile; (8) our dissolution without liquidation (*e.g.*, by a merger); or (9) any amendment to the Articles which would create or eliminate a supermajority requirement.

At shareholders' meetings, shareholders can be represented by proxy. However, a proxy must either be the shareholder's legal representative, another shareholder with the right to vote, a proxy appointed by us, an independent representative nominated by us, or a depositary. Votes are taken either by a show of hands or by electronic voting, unless the shareholders' meeting resolves to have a ballot or where a ballot is ordered by the chairman of the meeting.

The Directors' terms of office are coordinated so that in each year approximately one-third of all the Directors are subject to re-election or election. However, cumulative voting of shares is not permitted under Swiss law.

(c) Shareholders have the right to allocate the profit shown on our balance sheet by vote taken at the General Meeting of the Shareholders, subject to the legal requirements described in Item 10.B.3(a).

(d) Under Swiss law, any surplus arising out of a liquidation of our company (*i.e.*, after the settlement of all claims of all creditors) would be distributed to the shareholders in proportion to the paid-in nominal value of their shares.

(e) Swiss law limits a corporation's ability to hold or repurchase its own shares. We and our subsidiaries may only repurchase shares if we have free reserves equal to the purchase price to be paid for the shares. The aggregate nominal value of all Novartis shares held by us and our subsidiaries may not exceed 10% of the nominal value of our share capital. However, it is accepted that a corporation may repurchase its own shares beyond the 10% limit, if the repurchased shares are clearly dedicated for cancellation. In addition, we are required to create a special reserve on our balance sheet in the amount of the purchase price of the acquired shares. Repurchased shares held by us or our subsidiaries do not carry any rights to vote at the shareholders' meeting, but are entitled to the economic benefits generally connected with the shares. It should be noted that the definition of what constitutes subsidiaries, and therefore, treasury shares, for purposes of the above described reserves requirement and voting restrictions differs from the definition included in the consolidated financial statements. The definition in the consolidated financial statements requires consolidation for financial reporting purposes of special purpose entities, irrespective of their legal structure, in instances where we have the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities.

We may also repurchase shares for the purpose of capital reduction, which can only take place if the shareholders pass a resolution approving such reduction. We intend to propose to the next shareholders' meeting a reduction of our share capital of CHF 19,019,500.

(f) Not applicable.

(g) Since all of our issued and outstanding shares have been fully paid in, we can make no further capital calls on our shareholders.

(h) See Items 10.B.3(b) and 10.B.7.

#### **10.B.4** Changes To Shareholder Rights

Under Swiss law, we may not issue new shares without the prior approval of the shareholders. If a new issue is approved, then our shareholders would have certain preemptive rights to obtain newly issued shares in an amount proportional to the nominal value of the shares they already hold. These preemptive rights could be modified in certain limited circumstances with the approval of a resolution adopted at a shareholders' meeting by a supermajority of shares. In addition, we may not create shares with increased voting powers or place restrictions on the transfer of registered shares without the approval of a resolution adopted at a shareholders' meeting by a supermajority of shares. In addition, see Item 10.B.3(b) with regard to the Directors' ability to cancel the registration of shares under limited circumstances.

#### **10.B.5** Shareholder Meetings

Under Swiss law and the Articles, we must hold an annual ordinary shareholders' meeting within six months after the end of our financial year. Shareholders' meetings may be convened by the Board of Directors or, if necessary, by the statutory auditors. The Board is further required to convene an extraordinary shareholders' meeting if so resolved by a shareholders meeting, or if so requested by shareholders holding an aggregate of at least 10% of the registered shares, specifying the items for the agenda and their proposals. Shareholders holding shares with a nominal value of at least CHF 1,000,000 (*i.e.*, 2,000,000 Novartis shares) have the right to request that a specific proposal be put on the agenda and voted upon at the next shareholders meeting. A shareholders' meeting is convened by publishing a notice in the Swiss Official Commercial Gazette (*Schweizerisches Handelsamtsblatt*) at least 20 days prior to such meeting. Shareholders may also be informed by mail. There is no provision in the Articles requiring a quorum for the holding of a shareholders' meeting. In addition see Item 10.B.3(b) regarding conditions for exercising a shareholder's right to vote at a shareholders' meeting.

#### **10.B.6** Limitations

There are no limitations under Swiss law or our Articles on the right of non-Swiss residents or nationals to own or vote shares other than the restrictions applicable to all shareholders.

### 10.B.7 Change in Control

According to the Articles and the Swiss Code, shareholders may pass a resolution to merge with another corporation at any time. Such a resolution would require the consent of at least two-thirds of all votes present at the necessary shareholders' meeting.

Under the Swiss Stock Exchange Act, shareholders and groups of shareholders acting in concert who acquire more than 33<sup>1</sup>/<sub>3</sub>% of the voting rights of Novartis shares would be required to submit a takeover bid to all remaining shareholders. This mandatory bid obligation may be waived by the Swiss Takeover Board or the Swiss Federal Banking Commission under certain circumstances, in particular if another shareholder owns a higher percentage of voting rights than the acquirer. If no waiver is granted, the mandatory takeover bid would have to be made pursuant to the procedural rules set forth in the Swiss Stock Exchange Act and the ordinances enacted thereunder.

#### **10.B.8** Disclosure of Shareholdings

Under the Swiss Stock Exchange Act, holders of our voting shares would be required to notify us and the SWX of the level of their holdings whenever such holdings reach or exceed, or in some cases, fall short of, certain thresholds—5%, 10%, 20%,  $33\frac{1}{3}\%$ , 50% and  $66\frac{2}{3}\%$ —of our registered share capital, whether or not the shareholder has the right to cast votes based on the shares. Following receipt of such notification we would be required to inform the public by publishing the information in the Swiss Official Commercial Gazette and in at least one of the principal electronic media that disseminate stock exchange information.

An additional disclosure obligation exists under Swiss law which requires us to disclose the identity of all of our shareholders (or related groups of shareholders) who have been granted an exception entitling them to vote more than 2% of our shares, as described in Item 10.B.3(b). Under Swiss law, disclosure of shareholders entitled to vote more than 2% but less than 5% of our shares must only be made once a year, in the notes to the financial statements published in our annual report.

#### 10.B.9 Differences in the Law

See the references to Swiss law throughout this Item 10.B, which highlight certain key differences between Swiss and US law.

#### 10.B.10 Changes in Capital

The requirements of the Articles regarding changes in capital are not more stringent than the requirements of Swiss law.

#### **10.C Material contracts**

There are no material contracts other than those entered into in the ordinary course of business.

#### **10.D Exchange controls**

There are no Swiss governmental laws, decrees or regulations that restrict the export or import of capital, including any foreign exchange controls, or that affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold Novartis' shares.

#### **10.E Taxation**

The taxation discussion set forth below is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects relevant to the ownership or disposition of our shares or ADSs. The statements of US and Swiss tax laws set forth below are based on the laws and regulations in force as of the date of this 20-F, including the current Convention Between the United States and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, entered into force on December 19, 1997 (the "Treaty"), and the US Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations, rulings, judicial decisions and administrative pronouncements, and may be subject to any changes in US and Swiss law, and in any double taxation convention or treaty between the United States and Switzerland occurring after that date, which changes may have retroactive effect.

## **Swiss Taxation**

#### Swiss Residents

*Withholding Tax on Dividends and Distributions.* Dividends which we pay and similar cash or in-kind distributions which we may make to a holder of shares or ADSs (including distributions of liquidation proceeds in excess of the nominal value, stock dividends and, under certain circumstances, proceeds from repurchases of shares by us in excess of the nominal value) are subject to a Swiss federal withholding tax (the "Withholding Tax") at a current rate of 35%. We are required to withhold this Withholding Tax from the gross distribution and to pay the Tax to the Swiss Federal Tax Administration. The Withholding Tax is refundable in full to Swiss residents who are the beneficial owners of the taxable distribution at the time it is resolved and duly report the gross distribution received on their personal tax return or in their financial statements for tax purposes, as the case may be.

*Income Tax on Dividends.* A Swiss resident who receives dividends and similar distributions (including stock dividends and liquidation surplus) on shares or ADSs is required to include such amounts in the shareholder's personal income tax return. A corporate shareholder may claim substantial relief from taxation of dividends and similar distributions received if the shares held represent a fair market value of at least CHF 2 million.

*Capital Gains Tax upon Disposal of shares.* Under current Swiss tax law, the gain realized on shares held by a Swiss resident who holds shares or ADSs as part of his private property is generally not subject to any federal, cantonal or municipal income taxation on gains realized on the sale or other disposal of shares or ADSs. However, gains realized upon a repurchase of shares by us may be characterized as taxable dividend income if certain conditions are met. Book gains realized on shares or ADSs held by a Swiss corporate entity or by a Swiss resident individual as part of the shareholder's business property are, in general, included in the taxable income of such person. However, the Federal Law on the Direct Federal Tax of December 14, 1990 and several cantonal laws on direct cantonal taxes provide for exceptions for Swiss corporate entities holding more than 20% of our voting stock for more than one year.

#### **Residents of Other Countries**

Recipients of dividends and similar distributions on the shares who are neither residents of Switzerland for tax purposes nor holding shares as part of a business conducted through a permanent establishment situated in Switzerland ("Non-resident Holders") are not subject to Swiss income taxes in respect of such distributions. Moreover, gains realized by such recipients upon the disposal of shares are not subject to Swiss income taxes.

Non-resident Holders of shares are, however, subject to the Withholding Tax on dividends and similar distributions mentioned above and under certain circumstances to the Stamp Duty described below. Such Non-resident Holders may be entitled to a partial refund of the Withholding Tax if the country in which they reside has entered into a bilateral treaty for the avoidance of double taxation with Switzerland.

Non-resident Holders should be aware that the procedures for claiming treaty refunds (and the time frame required for obtaining a refund) may differ from country to country. Non-resident Holders should consult their own tax advisors regarding receipt, ownership, purchase, sale or other dispositions of shares or ADSs and the procedures for claiming a refund of the Withholding Tax.

As of January 1, 2005, Switzerland has entered into bilateral treaties for the avoidance of double taxation with respect to income taxes with the following countries, whereby a part of the above-mentioned Withholding Tax may be refunded (subject to the limitations set forth in such treaties):

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Albania	Hungary	Lithuania	Slovak Republic
Australia	Iceland	Luxembourg	Slovenia
Austria	India	Macedonia	South Africa
Belarus	Indonesia	Malaysia	Spain
Belgium	Iran	Mexico	Sri Lanka
Bulgaria	Israel	Moldavia	Sweden
Canada	Italy	Mongolia	Thailand
China	Ivory Coast	Morocco	Trinidad and Tobago
Croatia	Republic of Ireland	Netherlands	Tunisia
Czech Republic	Jamaica	New Zealand	Ukraine
Denmark	Japan	Norway	United Kingdom
Ecuador	Kazakhstan	Pakistan	United States of America
Egypt	Republic of Korea	Philippines	Uzbekistan
Estonia	(South Korea)	Poland	Venezuela
Finland	Kuwait	Portugal	Vietnam
France	Kyrgyzstan	Romania	Commonwealth of
Germany	Latvia	Russia	Independent States <sup>(1)</sup>
Greece		Singapore	-

(1) Excluding Estonia, Latvia, Lithuania and Russia.

Tax treaty negotiations are under way, or have been concluded, with Argentina (treaty not yet in force but provisionally applicable as from January 1, 2001), Armenia, Azerbaijan, Bangladesh, Brazil, Chile, Ethiopia, Georgia,, Peru, Tajikistan, Turkey, Turkmenistan, United Arab Emirates and Zimbabwe.

A Non-resident Holder of shares or ADSs will not be liable for any Swiss taxes other than the Withholding Tax described above and the Stamp Duty described below if the transfer occurs through or with a Swiss bank or other Swiss securities dealer. If, however, the shares or ADSs of Non-resident Holders can be attributed to a permanent establishment or a fixed place of business maintained by such person within Switzerland during the relevant tax year, the shares or ADSs may be subject to Swiss income taxes in respect of income and gains realized on the shares or ADSs and such person may qualify for a full refund of the Withholding Tax based on Swiss tax law.

Residents of the United States. A Non-resident Holder who is a resident of the United States for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 15% of the dividend, provided that such holder (i) qualifies for benefits under the Treaty, (ii) holds, directly and indirectly, less than 10% of our voting stock, and (iii) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares or ADSs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 15% Treaty rate. A Non-resident Holder who is a resident of the United States for purposes of the Treaty is eligible for a reduced rate of tax on dividends equal to 5% of the dividend, provided that such holder (i) is a company, (ii) qualifies for benefits under the Treaty, (iii) holds directly more than 10% of our voting stock, and (iv) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares or ADSs are attributable. Such an eligible holder must apply for a refund of the Treaty, (iii) holds directly more than 10% of our voting stock, and (iv) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares or ADSs are attributable. Such an eligible holder must apply for a refund of the amount of the Withholding Tax in excess of the 5% Treaty rate. Claims for refunds must be filed on Swiss Tax Form 82 (82C for corporations;

82I for individuals; 82E for other entities), which may be obtained from any Swiss Consulate General in the United States or from the Federal Tax Administration of Switzerland at the address below, together with an instruction form. Four copies of the form must be duly completed, signed before a notary public of the United States, and sent to the Federal Tax Administration of Switzerland, Eigerstrasse 65, CH-3003 Berne, Switzerland. The form must be accompanied by suitable evidence of deduction of Swiss tax withheld at source, such as certificates of deduction, signed bank vouchers or credit slips. The form may be filed on or after July 1 or January 1 following the date the dividend was payable, but no later than December 31 of the third year following the calendar year in which the dividend became payable. For US resident holders of ADSs, JPMorgan Chase Bank, N.A., as Depositary, will comply with these Swiss procedures on behalf of the holders, and will remit the net amount to the holders.

Stamp Duty upon Transfer of Securities. The sale of shares, whether by Swiss residents or Non-resident Holders, may be subject to federal securities transfer Stamp Duty of 0.15%, calculated on the sale proceeds, if the sale occurs through or with a Swiss bank or other Swiss securities dealer, as defined in the Swiss Federal Stamp Duty Act. The Stamp Duty has to be paid by the securities dealer and may be charged to the parties in a taxable transaction who are not securities dealers. Stamp Duty may also be due if a sale of shares occurs with or through a non-Swiss bank or securities dealer, provided (i) such bank or dealer is a member of the SWX, and (ii) the sale takes place on the SWX. In addition to this Stamp Duty, the sale of shares by or through a member of the SWX may be subject to a minor stock exchange levy.

#### **United States Federal Income Taxation**

The following is a general discussion of the material US federal income tax consequences of the ownership and disposition of our shares or ADSs that may be relevant to you if you are a US Holder (as defined below). Because this discussion does not consider any specific circumstances of any particular holder of our shares or ADSs, persons who are subject to US taxation are strongly urged to consult their own tax advisers as to the overall US federal, state and local tax consequences, as well as to the overall Swiss and other foreign tax consequences, of the ownership and disposition of our shares or ADSs. In particular, additional rules may apply to US expatriates, banks and other financial institutions, regulated investment companies, traders in securities who elect to apply a mark-to-market method of accounting, dealers in securities or currencies, tax-exempt entities, insurance companies, broker-dealers, investors liable for alternative minimum tax, investors that hold shares or ADSs as part of a straddle, hedging or conversion transaction, holders whose functional currency is not the US dollar, persons who acquired our shares pursuant to the exercise of employee stock options or otherwise and persons who hold directly, indirectly or by attribution, 10% or more of our outstanding share capital or voting power. This discussion generally applies only to US Holders who qualify for benefits under the Treaty and who are not also residents of Switzerland, who hold the shares or ADSs as a capital asset, and whose functional currency is the US dollar. Investors are urged to consult their own tax advisors concerning whether they are eligible for benefits under the Treaty.

For purposes of this discussion, a "US Holder" is a beneficial owner of Novartis shares or ADSs who is (i) a citizen or individual resident of the United States for US federal income tax purposes, (ii) a corporation (or other entity taxable as a corporation for US federal income tax purposes) created or organized in or under the laws of the US or a state thereof, (iii) an estate the income of which is subject to US federal income taxation regardless of its source, or (iv) a trust subject to the primary supervision of a US court and the control of one or more US persons. If a partnership (or other entity treated as a partnership for US federal income tax purposes) holds shares or ADSs, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. If a US Holder is a partner in a partnership that holds shares or ADSs, the Holder is urged to consult its own tax advisor regarding the specific tax consequences of owning and disposing of such shares or ADSs.

This discussion assumes that each obligation in the Deposit Agreement and any related agreement will be performed in accordance with its terms.

Dividends. For US federal income tax purposes, US Holders will be required to include the full amount (including the amount of any Withholding Tax) of a dividend paid with respect to our shares or ADSs as ordinary income. For this purpose, a "dividend" will include any distribution paid by us with respect to our shares or ADSs (other than certain pro rata distributions of our capital stock), as the case may be based on the US dollar value of the distribution calculated by reference to the spot rate in effect on the date the distribution is actually or constructively received by a US Holder, in the case of shares, or by the Depositary, in the case of ADSs. Such dividend will constitute income from sources outside the United States for US foreign tax credit purposes. Subject to the limitations and conditions provided in the Code, US Holders generally may claim as a credit against their US federal income tax liability, Withholding Tax withheld pursuant to the Treaty. The rules governing the foreign tax credit are complex. Each US Holder is urged to consult its own tax advisor concerning whether, and to what extent, a foreign tax credit will be available under the Treaty with respect to dividends received from us. Alternatively, a US Holder may claim the foreign taxes as a deduction for the taxable year within which they are paid or accrued, provided a deduction is claimed for all of the foreign taxes the US Holder pays in the particular year. A deduction does not reduce US tax on a dollar-for-dollar basis like a tax credit. The deduction, however, is not subject to the limitations applicable to foreign tax credits. Under the Code, dividend payments by us on the shares or ADSs are not eligible for the dividends received deduction generally allowed to corporate shareholders.

The US Treasury has expressed concern that parties to whom ADSs are released may be taking actions inconsistent with the claiming of foreign tax credits for US Holders of ADSs. Accordingly, the analysis above of the creditability of the Withholding Tax could be affected by future actions that may be taken by the US Treasury.

In general, a US Holder will be required to determine the amount of any dividend paid in Swiss francs, including the amount of any Withholding Tax imposed thereon, by translating the Swiss francs into US dollars at the spot rate on the date of receipt, regardless of whether the Swiss francs are in fact converted into US dollars. If a US Holder converts the Swiss francs so received into US dollars on the date of receipt, it generally should not recognize foreign currency gain or loss on such conversion. If a US Holder does not convert the Swiss francs so received into US dollars on the date of receipt, it will have a basis in the Swiss francs equal to the US dollar value on such date. Any foreign currency gain or loss that a US Holder recognizes on a subsequent conversion or other disposition of the Swiss francs generally will be treated as US source ordinary income or loss.

If a US Holder is a non-corporate US Holder the US dollar amount of any dividends paid to it prior to January 1, 2009 that constitute qualified dividend income generally will be taxable at a maximum rate of 15%, provided that the US Holder meets certain holding period and other requirements. We currently believe that dividends paid with respect to our shares and ADSs will constitute qualified dividend income for US federal income tax purposes. However, this is a factual matter and is subject to change. The US Treasury and the US Internal Revenue Service have announced their intention to promulgate rules pursuant to which US Holders of shares and ADSs, among others, will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. US Holders of shares or ADSs are urged to consult their own tax advisors regarding the availability to them of the reduced dividend rate in light of their own particular situation and the computations of their foreign tax credit limitation with respect to any qualified dividends paid to them, as applicable.

Sale or Other Disposition. Upon a sale or other disposition of shares or ADSs, US Holders generally will recognize capital gain or loss in an amount equal to the difference between the US dollar value of the amount realized on the disposition and the US Holder's tax basis (determined in US dollars) in the shares or ADSs. This capital gain or loss generally will be in US source gain or loss and will be treated as long-term capital gain or loss if the holding period in the shares or ADSs exceeds one year. In the case of certain US Holders (including individuals), any capital gain generally will be subject to US federal income tax at preferential rates if the US Holder meets the specified minimum holding periods. The deductibility of capital losses is subject to significant limitations.

United States Information Reporting and Backup Withholding. Dividend payments with respect to shares or ADSs and proceeds from the sale, exchange or other disposition of shares or ADSs may be subject to information reporting to the IRS and possible US backup withholding at a current rate of 28%. Certain exempt recipients (such as corporations) are not subject to these information reporting requirements. Backup withholding will not apply, however, to a Holder who furnishes a correct taxpayer identification number or certificate of foreign status and makes any other required certification or who is otherwise exempt from backup withholding. Any US Holders required to establish their exempt status generally must provide IRS Form W-9 (Request for Taxpayer Identification Number and Certification). Non-US holders generally are not subject to US information reporting or backup withholding requirements. However, such holders may be required to provide certification of non-US status (generally on IRS form W-8BEN) in connection with payments received in the United States or through US-related financial intermediaries. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a Holder's US federal income tax liability, and a Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information.

## 10.F Dividends and paying agents

Not applicable.

#### 10.G Statement by experts

Not applicable.

## 10.H Documents on display

Any statement in this Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Form 20-F the contract or document is deemed to modify the description contained in this Form 20-F. You must review the exhibits themselves for a complete description of the contract or document.

You may review a copy of our filings with the U.S. Securities and Exchange Commission (the "SEC"), including exhibits and schedules filed with it, at the SEC's public reference facilities in Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the SEC maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issues that file electronically with the SEC. These SEC filings are also available to the public from commercial document retrieval services.

WE ARE REQUIRED TO FILE REPORTS AND OTHER INFORMATION WITH THE SEC UNDER THE SECURITIES EXCHANGE ACT OF 1934. REPORTS AND OTHER INFORMATION FILED BY U.S. WITH THE SEC MAY BE INSPECTED AND COPIED AT THE SEC'S PUBLIC REFERENCE FACILITIES DESCRIBED ABOVE. AS A FOREIGN PRIVATE ISSUER, WE ARE EXEMPT FROM THE RULES UNDER THE EXCHANGE ACT PRESCRIBING THE FURNISHING AND CONTENT OF PROXY STATEMENTS AND OUR OFFICERS, DIRECTORS AND PRINCIPAL SHAREHOLDERS ARE EXEMPT FROM THE REPORTING AND SHORT SWING PROFIT RECOVERY PROVISIONS CONTAINED IN SECTION 16 OF THE EXCHANGE ACT. UNDER THE EXCHANGE ACT, AS A FOREIGN PRIVATE ISSUER, WE ARE NOT REQUIRED TO PUBLISH FINANCIAL STATEMENTS AS FREQUENTLY OR AS PROMPTLY AS UNITED STATES COMPANIES.

#### **10.I** Subsidiary Information

Not applicable.

# Item 11. Quantitative and Qualitative Disclosures about Non-Product-Related Market Risk

	Local Currencies	\$
2004		
Growth and currency contribution		
Net sales	9%	14%
Operating income	6%	11%
Net income	10%	15%
	Net sales	Costs
2004		
Net sales and operating costs by currencies:		
\$	43%	37%
Euro	26%	23%
CHF	3%	15%
Yen	8%	5%
Other	20%	20%
	100%	100%

	Liquid funds	Financial debt
2004		
Liquid funds and financial debt by currencies:		
\$	59%	21%
Euro	13%	36%
CHF	25%	40%
Yen	0%	0%
Other	3%	3%
	100%	100%

	Local	
	Currencies	\$
2003		
Growth and currency contribution:		
Net sales	11%	19%
Operating income	1%	16%
Net income	(8%)	6%

	Net sales	Costs
2003		
Net sales and operating costs by currencies:		
\$	43%	41%
Euro	26%	23%
CHF	4%	17%
Yen	8%	4%
Other		
	100%	100%
	Liquid funds	Financial
		debt
2003		
Liquid funds and financial debt by currencies:		
\$	50%	28%
Euro	15%	29%
CHF	32%	40%
Yen	1%	
Other	2%	3%
	100%	$\overline{100}\%$

#### **Market Risk**

We are exposed to market risk, primarily related to foreign exchange, interest rates and the market value of our investments of liquid funds. We actively monitor these exposures. To manage the volatility relating to these exposures, we enter into a variety of derivative financial instruments. Our objective is to reduce, where it is deemed appropriate to do so, fluctuations in earnings and cash flows associated with changes in interest rates, foreign currency rates and market rates of investments of liquid funds. It is our policy and practice to use derivative financial instruments to manage exposures and to enhance the yield on the investment of liquid funds. We do not enter any financial transactions containing a risk that cannot be quantified at the time the transaction is concluded. We only sell existing assets in transactions and future transactions (in the case of anticipatory hedges) which we confidently expect we will have in the future based on past experience. In the case of liquid funds, we write call options on assets we have or we write put options on positions we want to acquire and have the liquidity to acquire. We expect that any loss in value for those instruments generally would be offset by increases in the value of the underlying transactions.

*Foreign exchange rates:* We use the US dollar as our reporting currency and we are therefore exposed to foreign exchange movements, primarily in European, Japanese and other Asian and Latin American currencies. Consequently, we enter into various contracts which change in value as foreign exchange rates change, to preserve the value of assets, commitments and anticipated transactions. We use forward contracts and foreign currency option contracts to hedge certain anticipated net revenues in foreign currencies.

On December 31, 2004, we had long and short forward exchange and currency option contracts with equivalent values of \$5.8 billion and \$4.0 billion, respectively. At December 31, 2003, we had long and short forward exchange and currency option contracts with equivalent values of \$7.4 billion and \$4.0 billion, respectively.

Net investments in foreign countries are long-term investments. Their fair value changes through movements of the currency exchange rates. In the very long term, however, the difference in the inflation rate should match the exchange rate movement, so that the market value of the real assets abroad should compensate for the change due to currency movements. For this reason, we only hedge the net investments in foreign subsidiaries in exceptional cases.

*Commodities:* We have only a very limited exposure to price risk related to anticipated purchases of certain commodities used as raw materials by our businesses. A change in those prices may alter the gross margin of a specific business, but generally by not more than 10% of the margin and thus below materiality levels. Accordingly, we do not enter into significant commodity futures, forward and option contracts to manage fluctuations in prices of anticipated purchases.

*Interest rates:* We manage our net exposure to interest rate risk through the proportion of fixed rate debt and variable rate debt in our total debt portfolio. To manage this mix, we may enter into interest rate swap agreements, in which we exchange the periodic payments, based on a notional amount and agreed-upon fixed and variable interest rates. Our percentage of fixed rate debt to total financial debt was 47% at December 31, 2004, 51% at December 31, 2003 and 46% at December 31, 2002.

*Equity risk:* We purchase equities as investments of our liquid funds. As a policy, we limit our holdings in an unrelated company to less than 5% of our liquid funds. Potential investments are thoroughly analyzed in respect of their past financial track record (mainly cash flow return on investment), their market potential, their management and their competitors. Call options are written on equities which we own and put options are written on equities which we want to buy and for which cash has been reserved.

*Management summary:* Use of derivative financial instruments has not had a material impact on our financial position at December 31, 2004 and 2003 or on the results of our operations for the years ended December 31, 2004 and 2003.

*Value at risk:* We use a value at risk ("VAR") computation to estimate the loss in pre-tax earnings of our foreign currency price-sensitive derivative financial instruments, the potential ten-day loss of our equity holdings as well as the potential ten-day loss in the fair value of our interest rate-sensitive financial instruments. We use a ten-day period because it is assumed that not all positions could be undone in a single day, given the size of the positions. The VAR computation includes our debt, short-term and long-term investments, foreign currency forwards, swaps and options and anticipated transactions. Foreign currency trade payables and receivables as well as net investments in foreign subsidiaries are excluded from the computation.

The VAR estimates are made assuming normal market conditions, using a 95% confidence interval. We use a "Delta Normal" model to determine the observed inter-relationships between movements in interest rates, stock markets and various currencies. These inter-relationships are determined by observing interest rate, stock market movements and forward currency rate movements over a 60-day period for the calculation of VAR amounts.

The estimated potential ten-day loss in pre-tax earnings from foreign currency instruments under normal market conditions, the estimated potential ten-day loss on our equity holdings and the estimated potential ten-day loss in fair value of our interest rate-sensitive instruments, primarily debt and investments of liquid funds under normal market conditions, as calculated in the VAR model, follow:

	At Decer	nber 31,
	2004	2003
	(\$ mil	lions)
Instruments sensitive to foreign currency rates	382	244
Instruments sensitive to equity market movements	40	67
Instruments sensitive to interest rates	118	112
All instruments	495	356

The average, high, and low VAR amounts for 2004 are as follows:

	Average	High	Low
	(\$ 1		
Instruments sensitive to foreign currency rates	342	512	214
Instruments sensitive to equity market movements	53	84	37
Instruments sensitive to interest rates	177	501	108
All instruments	495	863	326

The VAR computation is a risk analysis tool designed to statistically estimate the maximum probable ten-day loss from adverse movements in foreign currency rates, equity market prices and interest rates under normal market conditions. The computation does not purport to represent actual losses in fair value or earnings to be incurred by us, nor does it consider the effect of favorable changes in market rates. We cannot predict actual future movements in such market rates and do not present these VAR results to be indicative of future movements in such market rates or to be representative of any actual impact that future changes in market rates may have on our future results of operations or financial position.

In addition to these VAR analyses, we use stress-testing techniques which are aimed at reflecting a worst case scenario. For these calculations, we use the worst movements during a period of six months over the past 20 years in each category. For 2004 and 2003, the worst case loss scenario was configured as follows:

	At December 31,	
	2004	2003
	(\$ millions)	
Bond portfolio	115	200
Money market and linked financial instruments	184	118
Equities	98	287
Foreign exchange risks	231	232
Total	628	837

In our risk analysis, we consider this worst case scenario acceptable inasmuch as it could reduce the income, but would not endanger our solvency and/or our investment grade credit standing. While it is highly unlikely that all worst case fluctuations would happen simultaneously, as shown in the model, the actual market can, of course, produce bigger movements in the future than it has historically. Additionally, in such a worst case environment management actions could further mitigate our exposure.

Our major financial risks are managed centrally by our Group Treasury. Only residual risks and some currency risks are managed by our affiliates. The collective amount of the residual risks is, however, below 10% of the global risks.

We have a written Treasury Policy, have implemented a strict segregation of front office and back office controls, and we do regular reconciliations of our positions with our counter parties. In addition, external audits of the Treasury function are performed at regular intervals.

#### Item 12. Description of Securities other than Equity Securities

Not applicable.

## Part II

# Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

# Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

None.

#### Item 15. Controls and Procedures

(a) Novartis AG's chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Novartis AG was made known to them by others within the company.

(b) *Report of Novartis Management on Internal Control Over Financial Reporting:* Novartis' Board of Directors and management of the Group are responsible for establishing and maintaining adequate internal control over financial reporting. The Novartis Group's internal control system was designed to provide reasonable assurance to the Novartis Group's management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of its published consolidated financial statements.

All internal control systems no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Novartis Group management assessed the effectiveness of the Group's internal control over financial reporting as of December 31, 2004. In making this assessment, it used the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our assessment management has concluded that, as of December 31, 2004, Novartis Group's internal control over financial reporting is effective based on those criteria.

Management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers AG, Switzerland (PwC), an independent registered public accounting firm, as stated in their report which is included under Item 18.

(c) See report of PwC, an independent registered public accounting firm, included under Item 18 on page F-2.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 16A. Audit Committee Financial Expert

Our Audit and Compliance Committee has determined that Prof. Ulrich Lehner, PhD, possesses the required accounting and financial management expertise required under the rules of the SEC. Therefore the Board of Directors has appointed him as the Audit and Compliance Committee's Financial Expert.

#### Item 16B. Code of Ethics

In addition to our Code of Conduct, which is applicable to all of our associates, we have adopted a code of ethics that imposes additional obligations on our principal executive officer, principal financial officer, principal accounting officer, and persons performing similar functions. This document is accessible on our Internet website at http://www.novartis.com/annual\_reports/2002/en/corp\_governance/governance 19.shtml.

#### Item 16C. Principal Accountant Fees and Services

#### Audit and Compliance Committee

Management is responsible for creating the financial statements and managing the reporting process. Further, management is responsible for designing internal controls over financial reporting and assessing and reporting on the effectiveness of those internal controls. The Audit and Compliance Committee (the "ACC") reviews the Group's financial reporting process on behalf of the Board of Directors.

For each quarterly and annual financial release, management's Disclosure Review Committee reviews the release for accuracy and completeness of the release's disclosures. The decisions taken by the Disclosure Review Committee are reviewed with the ACC before publication of the financial release.

The internal audit function, which reports to the Chairman and works closely with the ACC, reviews the effectiveness, efficiency and appropriateness of the internal control systems, particularly regarding the protection of assets, the completeness and accuracy of operational and financial information (with emphasis on internal reporting) and the adherence to Novartis Group guidelines.

Our independent auditor, PwC, is responsible for expressing an opinion on the conformity of the audited financial statements with International Financial Reporting Standards and compliance with Swiss law. Additionally, PwC is responsible for expressing an opinion on management's assessment of the effectiveness of internal control over financial reporting and an opinion on the effectiveness of internal control over financial reporting.

The ACC is responsible for overseeing the conduct of these activities by the Group's management and PwC. During 2004, the ACC held 8 meetings. PwC attended all meetings of the ACC and all matters of importance were discussed. PwC also attended one meeting of the Board of Directors of the Group. PwC provided to the ACC the written disclosures required by US Independence Standards Board Standard No. 1 (*Independence Discussions with Audit Committees*), and the ACC and PwC have discussed the auditors' independence from the Group and its management, including the matters in those written disclosures.

Based upon the reviews and discussions with management and the independent auditors referred to above, the ACC recommended to the Board of Directors, and the Board approved, inclusion of the audited financial statements in the Group's Annual Report for the year ended December 31, 2004.

#### Duration of the Mandate and Terms of Office of the Independent Auditors

The ACC proposed to the Board of Directors the independent auditor for election at the General Assembly. PwC assumed the existing auditing mandate for Novartis in 1996. The head auditors responsible for the mandate, Mr. James Kaiser and Mr. Daniel Suter, began serving in their roles in 2002 and 2003, respectively.

#### Policy on Pre-Approval of Audit and Non-Audit Services of Independent Auditors

Our ACC's policy is to pre-approve all audit and non-audit services provided by PwC. These services may include audit services, audit-related services, tax services and other services, as described below. Pre-approval is detailed as to the particular service or categories of services, and is subject to a specific budget.

PwC and management report to our ACC regarding the extent of services provided in accordance with this pre-approval and the fees for the services performed to date on a quarterly basis. Our ACC may also pre-approve additional services on a case-by-case basis.

### **Independent Auditor Fees**

The following fees were charged for professional services rendered by PwC for the 12-month period ended December 31:

	2004	2003
	(\$ thousands)	
Audit Services	19,561	13,360
Audit-Related Services	4,506	6,323
Tax Services	941	2,235
Other Services	8	2,742
Total	25,016	24,660

Audit Services are defined as the standard audit work that needs to be performed each year in order to issue opinions on the consolidated financial statements of the Group, to issue opinions relating to management's assessment of internal controls over financial reporting and the effectiveness of the Group's internal controls over financial reporting, and to issue reports on local statutory financial statements. Also included are services that can only be provided by the Group auditor such as auditing of nonrecurring transactions and application of new accounting policies, audits of significant and newly implemented system controls, pre-issuance reviews of quarterly financial results, consents and comfort letters and any other audit services required for US Securities and Exchange Commission or other regulatory filings.

Audit-Related Services include those other assurance services provided by the independent auditor but not restricted to those that can only be provided by the auditor signing the audit report. They comprise amounts for services such as acquisition due diligence, audits of pension and benefit plans, contractual audits of third party arrangements, assurance services on corporate citizenship reporting, and consultation regarding new accounting pronouncements.

Tax Services represent tax compliance and other services and expatriate and executive tax return services.

*Other Services* consist primarily of actuarial services for pension and employee benefit plans. As required by the Sarbanes-Oxley Act, PwC no longer provides certain of these services since May 2004. The total of audit-related, tax and other services was \$5,455,000 for 2004 and \$11,300,000 for 2003.

## Item 16D. Exemptions from the Listing Standards for Audit Committees

Not Applicable.

Total Number of Shares Purchased (a)	Average Price Paid per Share in \$ (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Maximum Approximate Value of Shares that may yet be purchased under the Plans or Programs in CHF (d)	Maximum Approximate Value of Shares that may yet be purchased under the Plans or Programs in \$ (e)
2,750,000	46.44	_	1,299,904,465	1,031,588,338
_	-	_	1,299,904,465	1,027,105,298
4,260,000	44.27	4,260,000	1,060,505,821	832,879,778
169,584	44.93	-	1,060,505,821	819,556,276
3,190,000	44.69	3,190,000	877,377,213	704,324,647
8,820,000	45.59	8,820,000	373,719,831	295,489,094
3,000,000	45.16	3,000,000	203,766,423	159,292,075
3,569,000	44.79	3,569,000	-	-
4,720,000	45.62	4,720,000	2,730,108,083	2,138,242,546
5,890,000	46.72	5,890,000	2.381,841,140	1,891,325,795
1,010,000	46.77	1,010,000	2,322,319,454	1,938,901,652
3,580,000	47.85	3,580,000	2,116,802,217	1,847,847,948
			2,116,802,217	1,865,928,174
40,958,584	45.73	38,039,000		
	Shares Purchased (a)           2,750,000           4,260,000           169,584           3,190,000           8,820,000           3,000,000           3,569,000           4,720,000           5,890,000           1,010,000           3,580,000	$\begin{array}{c c} \mbox{Total Number of Shares Purchased} \\ (a) \\ \hline \\ \hline \\ 2,750,000 \\ 46.44 \\ \hline \\ 4,260,000 \\ 44.27 \\ 169,584 \\ 44.93 \\ 3,190,000 \\ 44.69 \\ 8,820,000 \\ 45.59 \\ 3,000,000 \\ 45.16 \\ 3,569,000 \\ 44.79 \\ \hline \\ 4,720,000 \\ 45.62 \\ 5,890,000 \\ 46.72 \\ 1,010,000 \\ 46.77 \\ 3,580,000 \\ 47.85 \\ \hline \\ \hline \\ \hline \\ \end{array}$	Average Price Paid per Shares (a)         Shares Purchased as Part of Publicly Announced Plans or Programs (c)           2,750,000         46.44         -           2,750,000         46.44         -           4,260,000         44.27         4,260,000           169,584         44.93         -           3,190,000         45.59         8,820,000           3,000,000         45.16         3,000,000           3,569,000         45.62         4,720,000           4,720,000         46.72         5,890,000           1,010,000         46.77         1,010,000           3,580,000         47.85         3,580,000	$\begin{array}{c c c c c c c c c c c c c c c c c c c $

#### Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchaser

#### Note to column (a)

The shares purchased in January and April 2004 were purchased on the first trading line and not as part of a publicly announced repurchase program, as described in Item 5.B—"Liquidity and Capital Resources".

#### Notes to columns (c), (d) and (e)

- (1) The third share repurchase program was announced on July 22, 2002. The fourth share repurchase program was announced on August 9, 2004. These share repurchase programs are described in more detail in Item 5.B—"Liquidity and Capital Resources".
- <sup>(2)</sup> The third share repurchase program was approved for an amount of up to CHF 4.0 billion. The fourth share repurchase program was approved for an amount of up to CHF 3.0 billion.
- <sup>(3)</sup> The fourth share repurchase program is still ongoing. We did not define an expiration date for the program. We do not intend to terminate the fourth share repurchase program prior to the purchase of CHF 3.0 billion in shares.

<sup>(4)</sup> The third share repurchase program ended after the purchase of CHF 4.0 billion in shares on August 6, 2004.

<sup>(5)</sup> Column (e) shows in \$ the conversion of the CHF amount per month-end, using CHF/\$ exchange rate at the month-end.

# Part III

# Item 17. Financial Statements

Not applicable.

# Item 18. Financial Statements

The following financial statements are filed as part of this annual report on Form 20-F.

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### Item 19. Exhibits

- 1.1 Articles of Incorporation, as amended February 24, 2004 (in English translation).
- 1.2 Regulations of the Board and Committee Charters of Novartis AG, as amended April 15, 2003.\*
- 2.1 Restricted Issuance Agreement dated as of January 11, 2002 among Novartis AG, J.P. Morgan Chase & Co., as depositary, and all holders from time to time of ADRs issued thereunder (incorporated by reference from the Registration Statement on Form F-3, File No. 333-81862, as filed with the Commission on January 31, 2002).\*
- 2.2 Letter Agreement dated October 27, 2004 between Novartis AG and JPMorgan Chase Bank, as depositary.
- 4.1 The Leveraged Stock Saving Plan, Plan Summary-January 2002.\*
- 4.2 Agreement dated December 20, 2001 between Novartis International AG and Paul Choffat.\*
- 4.3 Agreement dated April 22, 2002 between Novartis Institute for Biomedical Research, Inc. and Mark C. Fishman, MD.\*
- 6.1 For Earnings per share calculation, see note 7 to our consolidated financial statements.
- 8.1 For a list of all of our principal Group subsidiaries and associated companies, see note 31 to our consolidated financial statements.
- 12.1 Certification of Daniel Vasella, Chairman and Chief Executive Officer of Novartis AG, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 12.2 Certification of Raymund Breu, Chief Financial Officer of Novartis AG, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 13.0 Certification of Daniel Vasella, Chairman and Chief Executive Officer of Novartis AG, and Raymund Breu, Chief Financial Officer of Novartis AG, pursuant to Section 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 14.1 Consent of PricewaterhouseCoopers AG to the incorporation by reference of the audit report contained in this Form 20-F into Novartis AG's Registration Statement on Form F-3 (File No. 333-81862) as filed with the SEC on January 31, 2002, on Form F-3 filed on May 11, 2002 (File No. 333-60712), on Form S-8 filed on May 14, 2001 (File No. 333-13506) and on Form S-8 filed on October 1, 2004 (File No. 333-119475).
  - \* Previously filed.

# SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

NOVARTIS AG

By: /s/ RAYMUND BREU

Name: Raymund Breu Title: *Chief Financial Officer, Novartis Group* 

# By: /s/ URS BÄRLOCHER

Name: Urs Bärlocher

Title: Head of Legal and General Affairs, Novartis Group

Date: January 28, 2005

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# NOVARTIS GROUP INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### **Report of Independent Registered Public Accounting Firm**

# To the Shareholders and Board of Directors of the Novartis Group, Basel

We have completed an integrated audit of the Novartis Group's 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements. Our opinions, based on our audits, are presented below.

#### **Consolidated financial statements**

We have audited the accompanying consolidated financial statements (balance sheet, income statement, cash flow statement, statement of changes in equity and notes) of the Novartis Group as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004. These consolidated financial statements are the responsibility of the Board of Directors and management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits of these statements in accordance with auditing standards promulgated by the Swiss profession and with International Standards on Auditing and the standards of the Public Company Accounting Oversight Board of the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Novartis Group at December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 in accordance with International Financial Reporting Standards (IFRS).

IFRS vary in certain respects from accounting principles generally accepted in the United States of America. Information relating to the nature and effect of such differences is presented in Note 32 to the consolidated financial statements.

#### Internal control over financial reporting

We have also audited management's assessment, included in the accompanying "Report of Novartis Management on Internal Control over Financial Reporting" appearing under Item 15(b), that Novartis maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Novartis' Board of Directors and management of the Group are responsible for maintaining effective internal control over financial reporting and management is responsible for the assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of Novartis Group's internal control over financial reporting based on our audit.

We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions. A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment, that the Novartis Group maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO. Also, in our opinion, the Novartis Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO. Also, is our opinion, the Novartis Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO.

PricewaterhouseCoopers AG

/s/ J.G. KAISER J.G. Kaiser /s/ D. SUTER D. Suter

Basel, January 19, 2005

## NOVARTIS GROUP CONSOLIDATED FINANCIAL STATEMENTS CONSOLIDATED INCOME STATEMENTS

(for the years ended December 31, 2004, 2003 and 2002)

	Notes	2004	2003	2002
<b>Net sales</b> Cost of Goods Sold <sup>(1)</sup>	3/4 3	(\$ millions) 28,247 (6,625)	(\$ millions) 24,864 (5,894)	(\$ millions) 20,877 (4,994)
Gross profit	3	<b>21,622</b> (8,873) (4,207) (1,540) (463)	<b>18,970</b> (7,854) (3,756) (1,381) (90)	<b>15,883</b> (6,737) (2,843) (1,146) (65)
Operating income	3/4 10 5	<b>6,539</b> 142 227	<b>5,889</b> (200) 379	<b>5,092</b> (7) 613
Income before taxes and minority interestsTaxes	6	<b>6,908</b> (1,126)	<b>6,068</b> (1,008)	<b>5,698</b> (959)
Income before minority interests          Minority interests          NET INCOME		<b>5,782</b> (15) <b>5 767</b>	<b>5,060</b> (44) <b>5,016</b>	<b>4,739</b> (14) <b>4,725</b>
Earnings per share (\$)	7	<b>5,767</b> 2.36	2.03	1.88
Diluted earnings per share (\$)	7	2.34	2.00	1.84

<sup>(1)</sup> Cost of Goods Sold omits amortization and impairment of acquired product and patent rights and trademarks which are included in Other income & expense. See note 3.

## NOVARTIS GROUP CONSOLIDATED FINANCIAL STATEMENTS CONSOLIDATED BALANCE SHEETS

(at December 31, 2004 and 2003)

	Notes	2004	2003
		(\$ millions)	(\$ millions)
ASSETS			
Long-term assets			
Property, plant & equipment	8	8,497	7,597
Intangible assets	9	5,629	4,708
Investments in associated companies	10	7,450	6,848
Deferred taxes	11	2,189	2,401
Financial and other assets	12	6,093	5,490
Total long-term assets		29,858	27,044
Current assets			
Inventories	13	3,558	3,346
Trade accounts receivable	14	4,851	4,376
Other current assets	15	1,609	1,292
Marketable securities & financial derivatives	16	8,510	7,613
Cash and cash equivalents		6,083	5,646
Total current assets		24,611	22,273
Total assets		54,469	49,317
EQUITY AND LIABILITIES			
Equity			
Share capital	17	1,008	1,017
Treasury shares	17	(127)	(121)
Reserves		32,902	29,533
Total equity		33,783	30,429
Minority interests		138	90
Liabilities			
Long-term liabilities			
Financial debts	18	2,736	3,191
Deferred taxes	11	3,384	3,138
Provisions and other long-term liabilities	19	3,350	3,149
Total long-term liabilities		9,470	9,478
Short-term liabilities			
Trade accounts payable		2,020	1,665
Financial debts	20	4,119	2,779
Other short-term liabilities	21	4,939	4,876
Total short-term liabilities		11,078	9,320
Total liabilities		20,548	18,798
TOTAL EQUITY, MINORITY INTERESTS AND LIABILITIES		54,469	49,317

### NOVARTIS GROUP CONSOLIDATED FINANCIAL STATEMENTS CONSOLIDATED CASH FLOW STATEMENTS

(for the years ended December 31, 2004, 2003 and 2002)

	Notes	2004	2003	2002
		(\$ millions)	(\$ millions)	(\$ millions)
Net income		5,767	5,016	4,725
Reversal of non-cash items		15	4.4	14
Minority interests		15 1,126	44 1,008	14 959
Depreciation, amortization and impairments on		1,120	1,000	939
Property, plant & equipment		796	768	622
Intangible assets		543	515	673
Financial assets		49	103	41
Result from associated companies		(142)	200	7 (133)
Gains on disposal of property, plant & equipment and intangible				(155)
assets		(223)	(325)	(260)
Net financial income		(227)	(379)	(613)
Dividends received		12	12	14
Interest and other financial receipts		379 (273)	501 (240)	435 (174)
Interest and other financial payments		(273)	62	(174)
Taxes paid		(1,083)	(842)	(769)
Cash flow before working capital and provision changes		6,812	6,443	5,585
Restructuring payments and other cash payments out of provisions		(219)	(248)	(204)
Change in net current assets and other operating cash flow items .	22	132	457	(152)
Cash flow from operating activities		6,725	6,652	5,229
Investment in property, plant & equipment		(1,269)	(1,329)	(1,068)
Proceeds from disposals of property, plant & equipment		129	92	183
Purchase of intangible assets		(181) 184	(214) 335	(90) 214
Proceeds from disposals of intangible assets		(747)	(816)	(725)
Proceeds from disposals of financial assets		486	632	582
Acquisition of additional interests in associated companies			(120)	(1,846)
Acquisition/divestment of a businesses	23	(1,031)	(272)	(542)
Acquisition of minorities		6.505	(10)	(2)
Proceeds from disposals of marketable securities		6,525 (7,315)	10,511 (10,107)	7,086
		<u> </u>		$\frac{(6,657)}{(6,657)}$
Cash flow used for investing activities		(3,219)	(1,298)	(2,865)
Acquisition of treasury shares		(1,874)	(273)	(3,228)
Dividend payments and cash contributions to minorities Proceeds from issuance of share capital to third parties by		(25)	(31)	(37)
subsidiaries		60		
Increase in long-term financial debts		14	18	999
Repayment of long-term financial debts		(15)	(31) (3,458)	(18)
Change in short-term financial debts		684	(265)	(390)
Dividends paid		(1,968)	(1,724)	(1,367)
Cash flow used for financing activities		(3,124)	(5,764)	(4,041)
Net effect of currency translation on cash and cash equivalents		55	258	836
Net change in cash and cash equivalents		437	(152)	(841)
Cash and cash equivalents at the beginning of the year		5,646	5,798	6,639
Cash and cash equivalents at end of the year		6,083	5,646	5,798

### NOVARTIS GROUP CONSOLIDATED FINANCIAL STATEMENTS

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

### (for the years ended December 31, 2004, 2003 and 2002)

	Notes	Share premium	<b>Retained</b> earnings	Fair value adjustments on marketable securities not recorded in net income	hedges not recorded in	in net income	Total reserves	Share capital	Treasury shares	Total equity
January 1, 2002		2,565	25,642	656	(10)	(\$ millions) (4,617)	24,236	1,047	(122)	25,161
Fair value adjustments on financial						<u>()</u> ,				
instruments	24a		98	(955)	123		(734)			(734)
movements			(74) 25			(30)	(104) 25			(104) 25
Translation effects						3,791	3,791			3,791
Net income			4,725				4,725			4,725
comprehensive income			4,774	(955)	123	3,761	7,703			7,703
Dividends	24d 24e		(1,367) (3,201)				(1,367) (3,201)		(27)	(1,367) (3,228)
Reduction in share capital			(3,201)				(3,201)	(22)	(27) 22	(3,220)
Total of other equity movements			(4,568)				(4,568)	(22)	(5)	(4,595)
December 31, 2002		2,565	25,848	(299)		(856)	27,371	1,025	(127)	28,269
Fair value adjustments on financial instruments	24a			332	(106)		226			226
Associated companies' equity movements	24b		(31)	41			10			10
Translation effects			~ /			2,363	2,363			2,363
Net income			5,016				5,016			5,016
comprehensive income			4,985	373	<u>(106</u> )	2,363	7,615			7,615
Dividends			(1,724) (271)				(1,724) (271)		(2)	(1,724) (273)
Repayment of call options on		(1.0.40)	. ,			(125)	~ /		(2)	
Novartis shares		(1,848)	92			(435)	(2,191)			(2,191)
Novartis shares		(541)	(603)			(123)	(1,267)	(8)	8	(1,267)
Total of other equity movements		(2,389)	(2,506)			(558)	(5,453)	(8)	6	(5,455)
December 31, 2003		176	28,327	74	7	949	29,533	1,017	(121)	30,429
Fair value adjustments on financial instruments	24a			297	(27)		270			270
Translation effects			24	26		1,099	50 1,099			50 1,099
Net income			5,767			1,099	5,767			5,767
Total of components of comprehensive income			5,791	323	(27)	1,099	7,186			7,186
Dividends	24d		(1,968)				(1,968)		(15)	(1,968)
Acquisition of treasury shares Reduction in share capital			(1,849)				(1,849)	(9)	(15) 9	(1,864)
Transfer to share premium		26	(26)							
Total of other equity movements December 31, 2004		$\frac{26}{202}$	$\frac{(3,843)}{30,275}$	397	(20)	2.048	$\frac{(3,817)}{32,902}$	$\frac{(9)}{1.008}$	(6)	(3,832)
December 31, 2004			30,275		(20)	2,048	32,902	1,008	(127)	33,783

#### 1. Accounting policies

The Novartis Group (Group or Novartis) consolidated financial statements are prepared in accordance with the historical cost convention except for the revaluation to market value of certain financial assets and liabilities and comply with the International Financial Reporting Standards (IFRS) formulated by the International Accounting Standards Board (IASB) and with International Accounting Standards (IAS) and interpretations formulated by its predecessor organization the International Accounting Standards Committee (IASC), as well as with the following significant accounting policies.

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual outcomes could differ from those estimates.

#### Scope of consolidation

The financial statements include all companies which Novartis AG, Basel, directly or indirectly controls (generally over 50% of voting interest).

Special purpose entities, irrespective of their legal structure, are consolidated in instances where the Group has the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities. As permitted by IFRS, equity compensation and post-employment plans are not consolidated.

Investments in associated companies (defined generally as investments of between 20% and 50% in a company's voting shares) and joint ventures are accounted for by using the equity method with the Group recording its share of the associated company's net income and equity.

#### **Principles of consolidation**

The annual closing date of the individual financial statements is December 31. The financial statements of consolidated companies operating in high-inflation countries are adjusted to eliminate the impact of high inflation.

The purchase method of accounting is used for acquired businesses. Companies acquired or disposed of during the year are included in the consolidated financial statements from the date of acquisition or up to the date of disposal.

The Group was formed on December 20, 1996 when all assets and liabilities of Sandoz AG and Ciba-Geigy AG were transferred by universal succession to Novartis AG. The uniting of interests method was used to account for this transaction. If it were undertaken today, the merger would require a different accounting treatment.

Intercompany income and expenses, including unrealized gross profits from internal Novartis transactions and intercompany receivables and payables have been eliminated.

#### Reclassification

Certain prior year balances have been reclassified to conform with the current year presentation.

#### Revenue and expense recognition

Revenue is recognized when title and risk of loss for the products is transferred to the customer. Provisions for rebates and discounts granted to government agencies, wholesalers, managed care and

#### 1. Accounting policies (Continued)

other customers are recorded as a reduction of revenue at the time the related revenues are recorded or when the incentives are offered. They are calculated on the basis of historical experience and the specific terms in the individual agreements. Cash discounts are offered to customers to encourage prompt payment. They are recorded as a reduction of revenue at the time of invoicing. Shelf-stock adjustments are granted to customers based on the existing inventory of a customer following decreases in the invoice or contract price of the related product. Provisions for shelf-stock adjustments are determined at the time of the price decline or at the point of sale if a price decline is reasonably estimable and based on estimated inventory levels. Where there is a historical experience of Novartis agreeing to customer returns, Novartis records a reserve for estimated sales returns by applying historical experience of customer returns to the amounts invoiced and the amount of returned products to be destroyed versus products that can be placed back in inventory for resale.

Expenses for research and service contracts in progress are recognized based on their percentage of completion.

#### **Foreign currencies**

The consolidated financial statements of Novartis are expressed in US dollars ("\$"). With effect from July 1, 2003, the measurement currency of certain Swiss and foreign finance companies used for preparing the financial statements has been changed to US dollars from the respective local currency. This reflects changes in these entities' cash flows and transactions now being primarily denominated in US dollars. Generally, the local currency is used as the measurement currency for other entities. In the respective entity financial statements, monetary assets and liabilities denominated in foreign currencies are translated at the rate prevailing at the balance sheet date. Transactions are recorded using the approximate exchange rate at the time of the transaction. All resulting foreign exchange transaction gains and losses are recognized in the subsidiary's income statement.

Income, expense and cash flows of the consolidated companies have been translated into US dollars using average exchange rates. The balance sheets are translated using the year end exchange rates. Translation differences arising from movements in the exchange rates used to translate equity and long-term intercompany financing transactions relating to the net investment in a foreign entity and net income are allocated to reserves.

#### Derivative financial instruments and hedging

Derivative financial instruments are initially recognized in the balance sheet at cost and subsequently remeasured to their fair value.

The method of recognizing the resulting gain or loss is dependent on whether the derivative contract is designed to hedge a specific risk and qualifies for hedge accounting. On the date a derivative contract is entered into, the Group designates derivatives which qualify as hedges for accounting purposes as either a) a hedge of the fair value of a recognized asset or liability (fair value hedge), or b) a hedge of a forecasted transaction or firm commitment (cash flow hedge) or c) a hedge of a net investment in a foreign entity.

Changes in the fair value of derivatives which are fair value hedges and that are highly effective are recognized in the income statement, along with any changes in the fair value of the hedged asset or liability that is attributable to the hedged risk. Changes in the fair value of derivatives in cash flow hedges are recognized in equity. Where the forecasted transaction or firm commitment results in the recognition

#### 1. Accounting policies (Continued)

of an asset or liability, the gains and losses previously included in equity are included in the initial measurement of the asset or liability. Otherwise, amounts recorded in equity are transferred to the income statement and classified as revenue or expense in the same period in which the forecasted transaction affects the income statement.

Hedges of net investments in foreign entities are accounted for similarly to cash flow hedges. The Group hedges certain net investments in foreign entities with foreign currency borrowings. All foreign exchange gains or losses arising on translation are recognized in equity and included in cumulative translation differences.

Certain derivative instruments, while providing effective economic hedges under the Group's policies, do not qualify for hedge accounting. Changes in the fair value of any derivative instruments that do not qualify for cash flow hedge accounting are recognized immediately in the income statement.

When a hedging instrument expires or is sold, or when a hedge no longer meets the criteria for hedge accounting, any cumulative gain or loss existing in equity at that time remains in equity and is recognized in the income statement, when the committed or forecasted transaction is ultimately recognized in the income statement. However, if a forecasted or committed transaction is no longer expected to occur, the cumulative gain or loss that was recognized in equity is immediately transferred to the income statement.

The purpose of hedge accounting is to match the impact of the hedged item and the hedging instrument in the income statement. To qualify for hedge accounting, the hedging relationship must meet several strict conditions with respect to documentation, probability of occurrence, hedge effectiveness and reliability of measurement. At the inception of the transaction the Group documents the relationship between hedging instruments and hedged items, as well as its risk management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives designated as hedges to specific assets and liabilities or to specific firm commitments or forecasted transactions. The Group also documents its assessment, both at the hedge inception and on an ongoing basis, as to whether the derivatives that are used in hedging transactions are highly effective in offsetting changes in fair values or cash flows of hedged items.

#### Property, plant & equipment

Property, plant & equipment have been valued at cost of acquisition or production cost and are depreciated on a straight-line basis to the income statement over the following estimated useful lives:

Buildings	20 to 40 years
Machinery and equipment	7 to 20 years
Furniture and vehicles	
Computer hardware	3 to 7 years

Land is valued at acquisition cost except if held under long-term lease arrangements, when it is amortized over the life of the lease. Land held under long-term lease agreements relates to upfront payments to lease land on which certain of the Group's buildings are located. Additional costs which extend the useful life of property, plant & equipment are capitalized. Financing costs associated with the construction of property, plant & equipment are not capitalized. Property, plant & equipment which are financed by leases giving Novartis substantially all the risks and rewards of ownership are capitalized at

#### 1. Accounting policies (Continued)

the lower of the fair value of leased property and the present value of minimum lease payments at the inception of the lease, and depreciated in the same manner as other property, plant & equipment over the shorter of the lease term or their useful life.

#### **Intangible assets**

Intangible assets are valued at cost and reviewed periodically for any diminution in value. Any resulting impairment loss is recorded in the income statement in Other Operating Income & Expense. In the case of business combinations, the excess of the purchase price over the fair value of net identifiable assets acquired is recorded as goodwill in the balance sheet. Goodwill, which is denominated in the local currency of the related acquisition, is amortized to income through other Operating Income & Expense on a straight-line basis over the asset's useful life. The amortization period is determined at the time of the acquisition, based upon the particular circumstances, and ranges from 5 to 20 years. An exception is for goodwill on acquisitions after March 31, 2004, which is no longer amortized under IFRS 3 but instead is subject to annual impairment testing. Goodwill relating to acquisitions arising prior to January 1, 1995, has been fully written off against retained earnings.

Up to March 31, 2004 management determined the estimated useful life of goodwill arising from an acquisition based on its evaluation of the respective company at the time of the acquisition, considering factors such as existing market share, potential sales growth and other factors inherent in the acquired company.

For all acquisitions after March 31, 2004, in accordance with IAS 38 (revised), In-Process Research & Development (IPR&D) is separately recorded as an intangible asset. It will start to be amortized when it results in a saleable product and is assessed at least annually for impairment.

Other acquired intangible assets are written off on a straight-line basis over the following periods:

Trademarks	10 to 15 years
Product and marketing rights	5 to 20 years
Software	3 years
Others	3 to 5 years

Trademarks are amortized on a straight-line basis over their estimated economic or legal life, whichever is shorter, while the practice of the Group has been to amortize product rights over estimated useful lives of 5 to 20 years. The useful lives assigned to acquired product rights are based on the maturity of the products and the estimated economic benefit that such product rights can provide. Marketing rights are amortized over their useful lives commencing in the year in which the rights first generate sales.

Long-lived property, plant & equipment and identifiable intangibles are reviewed for impairment whenever events or changes in circumstance indicate that the balance sheet carrying amount of the asset may not be recoverable. Goodwill is reviewed for impairment annually. When events or changes in circumstances indicate the value may not be fully recoverable, the Group estimates its value in use based on the future cash flows expected to result from the use of the asset and its eventual disposition. If the balance sheet carrying amount of the asset is more than the higher of its value in use to Novartis or its anticipated net selling price, an impairment loss for the difference is recognized. For purposes of assessing impairment, assets are grouped at the lowest level for which there are separately identifiable cash flows.

#### 1. Accounting policies (Continued)

Considerable management judgment is necessary to estimate discounted future cash flows. Accordingly, actual outcomes could vary significantly from such estimates.

#### **Financial assets**

Minority investments other than associated companies and joint ventures are initially recorded at cost on the trade date and subsequently carried at fair value and debt securities are carried at amortized cost. Exchange rate gains and losses on loans are recorded in the income statement. Originated loans are carried at amortized cost, less any allowances for uncollectable amounts. All other changes in the fair value of financial assets are deferred as a fair value adjustment to equity and recycled to the income statement when the asset is sold. Adjustments are made for other than temporary impairments in value.

#### Inventories

Purchased products are valued at acquisition cost while own-manufactured products are valued at manufacturing cost including related production expenses. In the balance sheet, inventory is primarily valued at standard cost, which approximates to historical cost determined on a first-in first-out basis, and this value is used for the cost of goods sold in the income statement. Provisions are made for inventories with a lower market value or which are slow-moving. If it becomes apparent that the inventory can be used, provisions are reversed with increases in the inventories' market value up to the original costs.

#### Trade accounts receivable

The reported values represent the invoiced amounts, less adjustments for doubtful receivables. Doubtful receivable provisions are established based upon the difference between the receivable value and the estimated net collectible amount.

#### Cash and cash equivalents

Cash and cash equivalents include highly liquid investments with maturities of three months or less. This position is readily convertible to known amounts of cash.

#### Marketable securities

Marketable securities consist of equity and debt securities which are traded in liquid markets. The Group has classified all its marketable securities as available-for-sale, as they are not acquired to generate profit from short-term fluctuations in price. All purchases and sales of marketable securities are recognized on the trade date, which is the date that the Group commits to purchase or sell the asset. Marketable securities are initially recorded at cost and subsequently carried at fair value. Exchange rate gains and losses on bonds are recorded in the income statement. All other changes in the fair value of unhedged securities are deferred as a fair value adjustment in equity and recycled to the income statement when the asset is sold or impaired. Where hedge accounting is applied, the change in fair value of effectively hedged securities is recorded in the income statement where it offsets the gains or losses of the hedging derivative.

Unrealized losses on marketable securities are included in Financial income, net in the income statement when there is objective evidence that the marketable securities are impaired. For 2004 the Group has amended its process to assess impairments of available-for-sale (AFS) marketable securities.

#### 1. Accounting policies (Continued)

Any security with a value less than market at the balance sheet date is now assessed for impairment (previously when the fair value was 50% of cost for a sustained period of six months).

#### **Repurchase agreements**

The underlying securities are included within marketable securities. The repurchase agreements for the securities sold and agreed to be repurchased under the agreement are recognized gross and included in short-term financial debts. Income and expenses are recorded in interest income and expense, respectively.

#### Taxes

Taxes on income are accrued in the same periods as the revenues and expenses to which they relate. Deferred taxes have been calculated using the comprehensive liability method. They are calculated on the temporary differences that arise between the tax base of an asset or liability and its carrying value in the balance sheet of Group companies prepared for consolidation purposes, except for those temporary differences related to investments in subsidiaries and associated companies, where the timing of their reversal can be controlled and it is probable that the difference will not reverse in the foreseeable future. Furthermore, withholding or other taxes on eventual distribution of retained earnings of Group companies are only taken into account where a dividend has been planned since generally the retained earnings are reinvested. Deferred tax assets or liabilities, calculated using applicable subsidiary tax rates, are included in the consolidated balance sheet as either a long-term asset or liability, with changes in the year recorded in the income statement. Deferred tax assets are fully recognized and reduced by a valuation allowance if it is probable that a benefit will not be realized in the future.

# Pension plans, post-employment benefits, other long-term employee benefits and employee share participation plans

#### a) Defined benefit pension plans

The liability in respect to defined benefit pension plans is in all material cases the defined benefit obligation calculated annually by independent actuaries using the projected unit credit method. The defined benefit obligation is measured at the present value of the estimated future cash flows. The charge for such pension plans, representing the net periodic pension cost less employee contributions, is included in the personnel expenses of the various functions where the employees are located. Plan assets are recorded at their fair values. Significant gains or losses arising from experience adjustments, changes in actuarial assumptions, and amendments to pension plans are charged or credited to income over the service lives of the related employees. Any pension asset recognized does not exceed the present value of future economic benefits available in the form of refunds from the plan and/or expected reductions in future contributions to the plan.

#### b) Post-employment benefits other than pensions

Certain subsidiaries provide health care and insurance benefits for a portion of their retired employees and their eligible dependents. The cost of these benefits is actuarially determined and included in the related function expenses over the employees' working lives. The related liability is included in long-term liabilities.

#### 1. Accounting policies (Continued)

#### c) Other long-term employee benefits

Other long-term employee benefits represent amounts due to employees under deferred compensation arrangements mandated by certain jurisdictions in which the Group conducts its operations. Benefit costs are recognized on an accrual basis in the personnel expenses of the various functions where the employees are located. The related obligation is accrued in other long-term liabilities.

#### *d) Employee share participation plans*

No compensation cost is recognized in these financial statements for options or shares granted to employees from employee share participation plans.

#### **Research and development**

Research and development expenses are fully charged to the income statement. The Group considers that regulatory and other uncertainties inherent in the development of its key new products preclude it from capitalizing development costs except for post-March 31, 2004 acquired IPR&D which is capitalized separately from goodwill. Other acquired projects that have achieved technical feasibility, usually confirmed by the US Food & Drug Administration or comparable regulatory body approval, are capitalized because it is probable that the costs will give rise to future economic benefits. Laboratory buildings and equipment included in property, plant & equipment are depreciated over their estimated useful lives.

#### **Government grants**

Government grants are deferred and recognized in the income statement over the period necessary to match them with the related costs which they are intended to compensate for.

#### **Restructuring charges**

Restructuring charges are accrued against operating income in the period in which management has committed to a plan and in which the a liability has been incurred and the amount can be reasonably estimated. Restructuring charges or releases are included in other operating expenses.

#### **Environmental liabilities**

Novartis is exposed to environmental liabilities relating to its past operations, principally in respect to remediation costs. Provisions for non-recurring remediation costs are made when expenditure on remedial work is probable and the cost can be estimated. Cost of future expenditures do not reflect any insurance or other claims or recoveries. The Group records insurance or other recoveries at such time the amount is reasonably estimable and collection is virtually certain. With regard to recurring remediation costs, the discounted amounts of such annual costs for the next 30 years are calculated and recorded in long-term liabilities.

#### Dividends

Dividends are recorded in the Group's financial statements in the period in which they are approved by the Group's shareholders.

#### 1. Accounting policies (Continued)

#### **Treasury shares**

Treasury shares are deducted from equity at their nominal value of CHF 0.50 per share. Differences between this amount and the amount paid for acquiring, or received for disposing of, treasury shares are recorded in retained earnings, net of tax.

#### 2. Changes in the scope of consolidation

Acquisitions prior to March 31, 2004 were accounted for in accordance with IAS 22. Acquisitions since April 1, 2004 are accounted for in accordance with IFRS 3 and goodwill is no longer amortized but instead is assessed annually for impairment.

The following significant changes in the scope of consolidation were made during 2004, 2003 and 2002:

#### **Acquisitions 2004**

#### Sandoz

On June 30, Novartis acquired 100% of the shares of the Danish generics company Durascan A/S from AstraZeneca. Goodwill of \$23 million has been recorded on this transaction.

On August 13, Novartis completed the acquisition of 100% of the shares of Sabex Inc., a Canadian generic manufacturer with a leading position in generic injectables, for \$565 million in cash. Based on a preliminary estimate, goodwill of \$329 million has been recorded on this transaction. In accordance with IFRS 3, the goodwill is no longer amortized. Instead it is assessed annually for impairment.

A total of \$61 million of sales and \$10 million of operating loss were recorded since the closure of these two transactions in 2004. The operating loss is mainly due to one-off costs related to purchase accounting and integration costs.

#### Medical Nutrition

On February 13, Novartis completed the acquisition of Mead Johnson's global adult medical nutrition business for \$385 million in cash. These activities are included in the consolidated financial statements from that date with \$220 million of sales and a \$31 million operating loss being recorded in 2004. The operating loss is mainly due to one-off costs related to purchase accounting and integration costs. Goodwill of \$183 million has been recorded on this transaction which is being amortized on a straight-line basis over 20 years.

#### **Acquisitions 2003**

#### Pharmaceuticals

On May 8, 2003 an additional 51% of the share capital of Idenix Pharmaceuticals Inc., Cambridge, Massachusetts was acquired for an initial payment of \$255 million in cash to its existing shareholders. As part of the acquisition, Novartis agreed to pay additional amounts to the shareholders of Idenix Pharmaceuticals Inc. based on the achievement of clinical and regulatory milestones, marketing approvals and sales targets. The total additional value of these milestone payments is up to \$357 million. Novartis cannot estimate when or if these additional milestone payments will be made. This company is included in

#### 2. Changes in the scope of consolidation (Continued)

the consolidated financial statements from May 2003. Since net liabilities were also assumed, total goodwill amounted to \$297 million on this transaction which is being amortized over 15 years.

#### Corporate

In 2003 the Group increased its investment in Roche Holding AG to 33.3% by acquiring further voting shares for \$120 million. The Group's holding represents approximately 6.3% of Roche Holding AG's total shares and equity instruments.

#### Acquisitions 2002

#### Sandoz

On November 29, 2002 the Business Unit acquired 99% of Lek d.d., Ljubljana, Slovenia for \$0.9 billion in cash. The acquisition was accounted for under the purchase method of accounting. A provisional balance sheet at December 31, 2002 was consolidated, however due to its immateriality, no post-acquisition income statement or cash flow was consolidated in 2002. During 2003 all the outstanding minority interests were acquired. In 2003, the initial assessment of goodwill resulting from the 2002 acquisition of Lek d.d., was finalized upon completion of a third-party valuation. As a result, the total goodwill initially recorded in 2002 of \$535 million was reduced by \$425 million through an allocation to the identifiable net assets acquired. The remaining goodwill balance of \$110 million is being amortized on a straight-line basis over 20 years.

#### Animal Health

In January 2002, the Business Unit completed the acquisition of two US farm animal vaccine companies, Grand Laboratories Inc., Iowa and ImmTech Biologies Inc., Kansas. The combined purchase price is a minimum of \$99 million of which \$78 million was settled in Novartis American Depositary Shares. The final price may increase depending on whether certain future sales and other targets are met. The acquisition was accounted for under the purchase method of accounting and the related goodwill was \$83 million which is being amortized on a straight-line basis over 15 years.

#### Corporate

During 2002, the Group increased its investment in Roche Holding AG by \$1.8 billion by acquiring a further 11.4% of this company's voting shares. In total 32.7% of the Roche Holding AG voting shares were held at December 31, 2002 which represented approximately 6.2% of Roche Holding AG's total shares and equity securities.

#### **Divestments 2004**

There were no significant divestments during 2004.

#### **Divestments 2003**

There were no significant divestments during 2003.

#### 2. Changes in the scope of consolidation (Continued)

#### **Divestments 2002**

#### Consumer Health Division

On November 29, 2002 the Division divested its Food & Beverage (F&B) business to Associated British Foods plc (ABF), London, Great Britain, for a total of \$270 million in cash. ABF acquired the F&B business and brand ownership worldwide (including the brands Ovaltine/Ovomaltine, Caotina and Lacovo) with the exception of the USA and Puerto Rico. The 2002 sales and operating income recorded by Novartis up to the November 29, 2002 divestment date amounted to \$209 million and \$8 million, respectively. This transaction produced a divestment gain of \$132 million which was recorded in Other Operating Income.

#### 3. Division and Business Unit Segmentation of key figures 2004, 2003 and 2002

#### **Operating Divisions**

Novartis is divided operationally on a worldwide basis into two Divisions, Pharmaceuticals and Consumer Health. These Divisions, which are based on internal management structures, are best described as follows:

The Pharmaceuticals Division researches, develops, manufactures, distributes, and sells branded pharmaceuticals in the following therapeutic areas: cardiovascular and metabolism, central nervous system, respiratory and dermatology, arthritis, bone therapy, gastrointestinal diseases, hormone replacement therapy and incontinence, infectious diseases, oncology and hematology, transplantation and immunology, ophthalmics. The Pharmaceuticals Division is organized into five Business Units: Primary Care, Oncology, Transplantation, Mature Products and Ophthalmics, which due to the fact that they have common long-term economic perspectives, customers, research, development, production, distribution and regulatory environments are not required to be separately disclosed as segments.

The Consumer Health Division consists of the following six Business Units:

The Sandoz Business Unit manufactures, distributes and sells generic pharmaceutical products and substances no longer subject to patent protection.

The Over-The-Counter (OTC) Business Unit manufactures, distributes and sells a variety of over-the-counter self medications.

The Animal Health Business Unit manufactures, distributes and sells veterinary products for farm and companion animals.

The Medical Nutrition Business Unit manufactures, distributes and sells health and medical nutrition products.

The Infant & Baby Business Unit manufactures, distributes and sells foods and other products and services designed to serve the particular needs of infants and babies.

The CIBA Vision Business Unit manufactures, distributes and sells contact lenses, lens care products, and ophthalmic surgical products.

#### 3. Division and Business Unit Segmentation of key figures 2004, 2003 and 2002 (Continued)

#### Corporate

Income and expenses relating to Corporate include the costs of the Group headquarters and those of corporate coordination functions in major countries. In addition, Corporate includes certain items of income and expense which are not directly attributable to specific Divisions. Usually, no allocation of Corporate items is made to the Divisions although there are charges made by Corporate for share and share option programs and certain pension plans.

The Group's Divisions are businesses that offer different products. These Divisions are managed separately because they manufacture, distribute, and sell distinct products which require differing technologies and marketing strategies.

Revenues on inter-Divisional and inter-Business Unit sales are determined on an arm's length basis. The accounting policies of the Divisions and Business Units described above are the same as those described in the summary of accounting policies except that they receive a Corporate charge for share and share option programs which have no net cost in the Group's IFRS consolidated financial statements. The Group principally evaluates Divisional and Business Unit performance and allocates resources based on operating income.

Division and Business Unit net operating assets consist primarily of property, plant & equipment, intangible assets, inventories and receivables less operating liabilities. Corporate assets and liabilities principally consist of net liquidity (cash, cash equivalents, marketable securities less financial debts), investments in associated companies and deferred and current taxes.

### CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 3. Division and Business Unit Segmentation of key figures 2004, 2003 and 2002 (Continued)

			<b>Consumer Health Business Units</b>								
2004	Pharmaceuticals Division		Sandoz	отс		Medical Nutrition			Divisional management costs & eliminations		Total
Net sales to third parties		<b>9,750</b> 98	<b>3,045</b> 97	<b>1,975</b> 29		<b>1,121</b> 7	1,441	<b>1,412</b> 12	(47)	(244)	28,247
Sales of Divisions/Business Units	18,643	9,848	3,142	2,004	756	1,128	1,441	1,424	(47)	(244)	28,247
Cost of Goods Sold	(2,568)	(4,310)			_	_		_	_	253	(6,625)
Gross profit	(6,099) (3,480) (641)	<b>5,538</b> (2,774) (566) (573) (444)								9 (161) (326) 583	<b>21,622</b> (8,873) (4,207) (1,540) (463)
Operating income	5,253	1,181	235	351	78	32	274	236	(25)	105	6,539
Result from associated companies		2	2							106	142 227
Income before taxes and minority interests											<b>6,908</b> (1,126)
Income before minority interests											<b>5,782</b> (15)
Net income											5,767
Included in operating income are: Research and development Depreciation of property, plant & equipment Amortization of product rights, patent rights and trademarks Amortization of other intangible assets and goodwill Impairment charges on property, plant & equipment	(434) (160) (32)	(566) (314) (128) (128) (14)	(286) (170) (69) (41) (16)	(20 (18 (2	(11) (11) (6)	(20) (13) (10) (21) 4	(29) (31) (1) (24)	(65) (69) (24) (26) (2)		$(161) \\ (32) \\ (8) \\ (2)$	(4,207) (780) (288) (168) (16)
Impairment charges on product rights, patent rights and trademarks	(12)	(75)	(75)	1							(12) (75)
Thereof amortization and impairments on product rights, patent rights and trademarks charged to other income & expense <sup>(1)</sup> Restructuring charges	(157) (10)	(107) (21)	(57) (21)	(16	)	(10)		(24)			(264) (31)
Royalties Income Expense		19 (39)	6 (4)	8 (16)	) (12)	2 (3)		2 (4)			60 (343)
Total assets		<b>11,494</b> (3,159)		<b>1,198</b> (492)		<b>933</b> (326)	<b>1,903</b> (986)	1,522 (351)	( <b>68</b> ) 50	<b>28,061</b> (11,971)	<b>54,469</b> (20,548)
Total equity and minority interests		8,335	4,493	706	459	607	917	1,171	(18)	<b>16,090</b> (7,738)	<b>33,921</b> (7,738)
Net operating assets	9,496	8,335	4,493	706		607	917	1,171	(18)	8,352	26,183
Included in total assets are: Total property, plant & equipment Additions to property, plant & equipment Additions to intangible assets Total investments in associated companies	716 116	2,761 522 602 25	1,797 329 368 25	163 16 3	86 15	101 10 186	264 54 43	350 98 2	_	357 31 6,279	8,497 1,269 718 7,450
Employees at year end (unaudited)	47,325	32,548	13,397	4,047	2,248	2,948	4,385	5,479		1,519	81,392

(1) Under US GAAP reclassified to Cost of Goods Sold.

### CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 3. Division and Business Unit Segmentation of key figures 2004, 2003 and 2002 (Continued)

			<b>Consumer Health Business Units</b>								
2003	Pharmaceuticals Division			отс		Medical Nutrition			Divisional management costs & eliminations	Corporate	Total
Net sales to third parties		<b>8,844</b> 98	<b>2,906</b> 139		682	<b>815</b> 1	1,361	<b>1,308</b> 8	(64)	(231)	24,864
Sales of Divisions/Business Units	16,153	8,942	3,045		682	816	1,361	1,316	(64)	(231)	24,864
Cost of Goods Sold	(2,360)	(3,768)		_	_					234	(5,894)
Gross profit Marketing & Sales Research & Development General & Administration Other income & expense	(5,322) (3,079) (582)	<b>5,174</b> (2,532) (529) (485) (308)								<b>3</b> (148) (314) 605	<b>18,970</b> (7,854) (3,756) (1,381) (90)
Operating income	4,423	1,320	473	309	88	82	254	153	(39)	146	5,889
Result from associated companies	136	3	3							(339)	(200) 379
Income before taxes and minority interests											<b>6,068</b> (1,008)
Income before minority interests											<b>5,060</b> (44)
Net income											5,016
Included in operating income are: Research and development Depreciation of property, plant & equipment Amortization of product rights, patent rights and trademarks Amortization of other intangible assets and goodwill Impairment charges on property, plant & equipment Impairment charges on product rights, patent rights and trademarks Impairment charges on product rights, patent rights and trademarks Impairment charges on product rights, patent rights and trademarks	(424) (165) (22) (26)	(529) (285) (106) (114) (5) (17) (76)	(263) (143) (54) (45) (72)	(23 (15 (3	) (5)	(15) (12) (3) (3) (4)	(28) (30) (2) (21)	(74) (67) (27) (28) (1) (17) (4)		(148) (28) (3)	(3,756) (737) (271) (139) (31) (17) (88)
Thereof amortization and impairments on product rights, patent rights and trademarks charged to other income & expense <sup>(1)</sup>	· · · ·	(104)	(45)		``	(1)	(2)	(43)			(260)
Restructuring charges	(150)	(104)	(45)	(15	)	(1)	(2)	(43)			(200)
Royalties Income Expense		8 (20)	1 (8)	4 (6	) (1)			3 (5)			66 (276)
Total assets		<b>9,689</b> (2,962)		<b>1,032</b> ) (434		<b>468</b> (211)	<b>1,684</b> (880)	1,573 (340)	( <b>49</b> ) 7	<b>25,792</b> (10,969)	<b>49,317</b> (18,798)
Total equity and minority interests		6,727	3,371	598	506	257	804	1,233	(42)	14,823 (7,289)	<b>30,519</b> (7,289)
Net operating assets		6,727	3,371			257	804	1,233	(42)	7,534	23,230
Included in total assets are: Total property, plant & equipment Additions to property, plant & equipment Additions to intangible assets. Total investments in associated companies	771 359	2,434 530 186 23	1,532 388 82 23		79 13	98 11 33	242 29 39	322 69 11		335 28 5,705	7,597 1,329 545 6,848
Employees at year end (unaudited)	44,640	32,464	12,918	3,920		2,849	4,829	5,717	38	1,437	78,541

(1) Under US GAAP reclassified to Cost of Goods Sold.

CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 3. Division and Business Unit Segmentation of key figures 2004, 2003 and 2002 (Continued)

			<b>Consumer Health Business Units</b>									
2002	Pharmaceuticals Division					Medical Nutrition			Functional Food	Divisional management costs & eliminations	Corporate	Total
					(\$ n	illions exc	ept empl	oyees)				
Net sales to third parties		<b>7,349</b> 104	<b>1,817</b> 130	<b>1,521</b> 12	623	<b>711</b> 8	1,333	1,135 8	209	(54)	(215)	20,877
Sales of Divisions/Business Units	13,639	7,453	1,947	1,533	623	719	1,333	1,143	209	(54)	(215)	20,877
Cost of Goods Sold	(2,017)	(3,200)									223	(4,994)
Gross profit Marketing & Sales Research & Development . General & Administration Other income & expense	(4,574) (2,355) (492)	<b>4,253</b> (2,163) (378) (419) (207)									<b>8</b> (110) (235) 452	<b>15,883</b> (6,737) (2,843) (1,146) (65)
Operating income	3,891	1,086	265	240	92	4	227	118	140		115	5,092
Result from associated companies	109	1	1								(117)	(7) 613
Income before taxes and minority interests												<b>5,698</b> (959)
Income before minority interests												<b>4,739</b> (14)
Net income												4,725
Included in operating income are: Research and development . Depreciation of property, plant & equipment . Amortization of product rights, patent rights and trademarks . Amortization of other intangible assets and goodwill . Impairment charges on property, plant & equipment . Impairment charges on product rights, patent rights and trademarks . Impairment charges on other intangible assets and goodwill . Thereof amortization and impairments on product rights, patent rights and trademarks . Thereof amortization and impairments on product rights, patent rights and trademarks .	$ \begin{array}{c} (351)\\(165)\\(19)\\(14)\\(63)\\(202)\end{array} $	(378) (222) (62) (103) (15) (14) (34)	(139) (83) (19) (32) (13) (1)	(67) (21) (10) (2)		(16) (20) (2) (3)	$(23) \\ (24) \\ (4) \\ (21) \\ (2) \\ (11) \\ (14) \\ (14) \\ (23) \\ (14) \\ (1$	(70) (65) (24) (32) (4)	(3) (2) (16)		(110) (19) (6) (6)	(2,843) (592) (227) (128) (29) (77) (242)
charged to other income and expense <sup>(1)</sup>	(220)	(47)	(12)				(4)	(23)				(267)
Restructuring charges		(58) 132		(10)		(28)			(20) 132			(58) 133
Income		5 (14)	1	1	(1)			3 (9)				65 (211)
Expense		(14) 8,419	(1) 3.329	(3) 902	(1) 603	385	1,620	1,626		(46)	24,664	(211) 45,025
Liabilities		(2,625)		(331)		(243)	(871)	(306)		46	(10,164)	(16,690)
Total equity and minority interests		5,794	2,548	571	464	142	749	1,320			<b>14,500</b> (6,972)	<b>28,335</b> (6,972)
Net operating assets		5,794	2,548	571	464	142	749	1,320			7,528	21,363
Included in total assets are: Total property, plant & equipment	505 2 1,000 44,110	1,877 361 684 18 27,552	990 214 558 18 <b>7,932</b>	169 24 25 3,797	71 10 96 2,218	93 29 <b>2,701</b>	233 44 <b>4,901</b>	321 40 5 <b>6,003</b>			460 202 18 5,465 <b>1,215</b>	6,321 1,068 704 6,483 <b>72,877</b>
				_		_	—					

(1) Under US GAAP reclassified to Cost of Goods Sold.

### 4. Supplementary Segmentation of key figures 2004, 2003 and 2002

### **Geographical segmentation**

2004	Europe	The Americas	Asia/Africa Australia	Total
		(in \$ millions ex		
Net sales <sup>(1)</sup> $\ldots$ $\ldots$ $\ldots$ $\ldots$ $\ldots$ $\ldots$ $\ldots$	10,289	13,285	4,673	28,247
Operating income <sup>(2)</sup>	4,625	1,417	497	6,539
Depreciation of property, plant & equipment included in		,		
operating income	510	229	41	780
Net operating assets <sup>(3)</sup>	18,230	6,702	1,251	26,183
Additions to property, plant & equipment included in				
net operating assets	787	340	142	1,269
Additions to intangible assets	33	660	25	718
Personnel costs	3.401	3.011	572	6,984
Employees at year end <sup>(4)</sup>	38,229	30,186	12,977	81,392

2003	Europe	The Americas	Asia/Africa Australia	Total
Net sales <sup>(1)</sup> Operating income <sup>(2)</sup>	8,788 4,505	(in \$ millions ex 12,036 897	cept employees) 4,040 487	24,864 5,889
Depreciation of property, plant & equipment included in operating income	480 <b>16,271</b>	220 <b>5,984</b>	37 <b>975</b>	737 <b>23,230</b>
Additions to property, plant & equipment included in net operating assets         Additions to intangible assets         Personnel costs         Employees at year end <sup>(4)</sup>	846 120 3,002 <b>37,510</b>	427 424 2,759 <b>28,608</b>	56 1 491 <b>12,423</b>	1,329 545 6,252 <b>78,541</b>

2002	Europe	The Americas	Asia/Africa Australia	Total
		(in \$ millions ex	cept employees)	
Net sales <sup>(1)</sup>	6,832	10,558	3,487	20,877
Operating income <sup>(2)</sup>	3,825	958	309	5,092
Depreciation of property, plant & equipment included in				
operating income	355	198	39	592
Net operating assets <sup>(3)</sup>	14,086	6,312	965	21,363
Additions to property, plant & equipment included in				
net operating assets	498	537	33	1,068
Additions to intangible assets	565	126	13	704
Personnel costs	2,279	2,408	441	5,128
Employees at year end <sup>(4)</sup>	32,595	28,328	11,954	72,877

Net sales by location of third party customer. (1)

Operating income as recorded in the legal entities in the respective region. (2)

(3) Long-term and current assets (excluding marketable securities, cash and time deposits) less non-interest bearing liabilities.

(4) Unaudited.

#### CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 4. Supplementary Segmentation of key figures 2004, 2003 and 2002 (Continued)

The following countries accounted for more than 5% of at least one of the respective Group totals as at, or for the years ended, December 31, 2004, 2003 and 2002:

(in \$ millions)			Net sal	es <sup>(1)</sup>			Additi	ons to	property,	plant	& equipr	nent		Ne	et operatin	g asset	s <sup>(2)</sup>	
Country	2004	%	2003	%	2002	%	2004	%	2003	%	2002	%	2004	%	2003	%	2002	%
Switzerland	330	1	319	1	317	2	226	18	177	13	124	12	12,204	47	10,631	46	9,238	43
USA	11,258	40	10,280	41	8,907	43	302	24	388	29	511	48	6,316	24	6,149	26	6,056	28
Japan	2,424	9	2,065	8	1,701	8	21	2	14	1	5		1,113	4	857	4	617	3
Germany	1,596	6	1,479	6	1,226	6	36	3	39	3	45	4	(121)		30		173	1
France	1,692	6	1,423	6	1,100	5	19	1	17	1	18	2	780	3	690	3	644	3
UK	979	3	789	3	680	3	154	12	194	15	79	7	1,180	5	1,008	4	863	4
Austria	245	1	224	1	179	1	106	8	170	13	131	12	1,043	4	946	4	613	3
Slovenia	112		103		24		130	10	103	8			1,222	5	1,048	5	822	4
Singapore	23		20		19		70	6	9	1	2		82		17		5	
Other	9,588	34	8,162	34	6,724	32	205	16	218	16	153	_15	2,364	8	1,854	8	2,332	11
Total Group	28,247	<u>100</u>	24,864	100	20,877	100	1,269	<u>100</u>	1,329	100	1,068	100	26,183	100	23,230	100	21,363	100

<sup>(1)</sup> Net sales by location of third party customer.

<sup>(2)</sup> Long-term and current assets (excluding marketable securities, cash and time deposits) less non-interest bearing liabilities.

One customer accounts for approximately 10% of Group net sales in 2004. No other customer accounts for 10% or more of the Group's total net sales.

Pharmaceutical Division therapeutic area net sales Therapeutic area	2004	2003	2002
	(\$	(\$	(\$
	millions)	millions)	millions)
Cardiovascular			
Strategic franchise products Diovan	3.093	2,425	1,662
Lotrel	920	777	650
Lescol	758	734	577
Other	120	116	99
Total strategic franchise products <sup>(1)</sup>	4,891 815	4,052 1,064	2,988 1,106
Total Cardiovascular products	5,706	5,116	4,094
Nervous system			
Strategic franchise products	518	397	279
Trileptal	422	367	304
Tegretol	396	384	364
Other	686	595	518
Total strategic franchise products <sup>(1)</sup>	2,022	1,743	1,465
Mature products	533	505	506
Total Nervous System products	2,555	2,248	1,971
Respiratory/Dermatology			
Strategic franchise products Lamisil	1,162	978	873
Elidel	349	235	95
Foradil	321	289	262
Other	43	29	15
Total strategic franchise products <sup>(1)</sup>	1,875 151	1,531 154	1,245 161
Total Respiratory/Dermatology products	2,026	1,685	1,406
Oncology			
Gleevec/Glivec	1,634	1,128	614
Zometa	1,078 827	892 695	488 607
Femara	386	227	175
Other	290	359	548
Total Oncology products	4,215	3,301	2,432
Transplantation			
Neoral/Sandimmun Other	1,011 81	1,020 61	1,036 66
Total Transplantation products	1,092	1,081	1,102
Ophthalmics			
Visudvne	448	357	287
Other	327	262	282
Total Ophthalmics products	775	619	569
Arthritis/Bone/Gastrointestinal/Hormonal/Infectious diseases/other			
Strategic franchise products			
Zelnorm/Zelmac	299 269	165 240	45 249
Total strategic franchise products <sup>(1)</sup>	568	405	294
Mature products	1,560	1,565	1,660
$Total \ Arthritis/Bone/Gastrointestinal/ \ Hormonal/Infectious \ diseases/other \ products \ \ . \ .$	2,128	1,970	1,954
Total strategic franchise products <sup>(1)</sup>	15,438	12,732	10,095
Total mature products	3,059	3,288	3,433
Total	18,497	16,020	13,528

# 4. Supplementary Segmentation of key figures 2004, 2003 and 2002 (Continued) Pharmaceutical Division therapeutic area net sales

(1) Strategic franchise products are products actively supported by the Pharmaceutical Division Primary Care Business Unit.

### 5. Financial income, net

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Interest income	388	323	416
Dividend income	12	17	68
Net capital gains	123	11	
Income on options and forward contracts	306	1,113	1,659
Other financial income	7	9	3
Financial income	836	1,473	2,146
Interest expense	(261)	(243)	(194)
Net capital losses			(79)
Impairment of marketable securities	(66)	(66)	
Expenses on options and forward contracts	(332)	(809)	(1,261)
Other financial expense	(46)	(40)	(68)
Financial expense	(705)	(1,158)	(1,602)
Currency result, net	96	64	69
Total financial income, net	227	379	613

2004 interest income includes a total of \$3 million (2003: \$9 million; 2002: \$19 million) received from the foundations referred to in Note 27 at commercial interest rates on the outstanding short-term debt.

### 6. Taxes

Income before taxes and minority interests:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Switzerland	3,517	2,809	2,491
Foreign	3,391	3,259	3,207
Total income before taxes and minority interests	6,908	6,068	5,698

### 6. Taxes (Continued)

Current and deferred income tax expense:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Switzerland	(259) (597)	(330) (765)	(273) (476)
Total current income tax expense	(856)	(1,095)	(749)
Switzerland	(67) (133)	(9) 177	(46) (152)
Total deferred tax income & expense	(200)	168	(198)
Share of tax of associated companies	(70)	(81)	(12)
Total income tax expense	(1,126)	(1,008)	(959)

The gross value of unused tax loss carryforwards which have, or have not, been capitalized as deferred tax assets, with their expiry dates is as follows:

	Not capitalized	Capitalized	2004
	(\$ millions)	(\$ millions)	(\$ millions)
One year	10		10
Two years	12		12
Three years	14	4	18
Four years	69	13	82
Five years	718	5	723
More than five years	355	180	535
Total	1,178	202	1,380

	Not capitalized	Capitalized	2003
	(\$ millions)	(\$ millions)	(\$ millions)
One year	8	17	25
Two years	4	20	24
Three years	9	42	51
Four years	73	29	102
Five years	45	7	52
More than five years	881	109	990
Total	1,020	224	1,244

Tax losses are capitalized if it is probable that future taxable profits will arise to utilize the losses.

\$4 million of unused operating tax loss carryforwards expired during 2004 (2003: \$33 million; 2002: \$2 million).

#### 6. Taxes (Continued)

#### Analysis of tax rate

The main elements contributing to the difference between the Group's overall expected tax rate (the weighted average tax rate based on the income before tax of each subsidiary) and the effective tax rate are:

	2004	2003	2002
	%	%	%
Expected tax rate	16.8	14.8	15.3
Effect of taxes of associated companies	0.7	1.9	0.3
Effect of disallowed expenditures	1.8	2.3	2.4
Effect of utilization of tax losses brought forward from prior periods	(0.4)	(0.6)	(0.5)
Effect of income taxed at reduced rates	(0.5)	(2.0)	(1.3)
Effect of tax credits and allowances	(1.7)	(1.4)	(1.0)
Effect of write-off of deferred tax assets	0.1	0.5	0.6
Prior year and other items	(0.5)	1.1	1.0
Effective tax rate	16.3	16.6	16.8

The utilization of tax loss carryforwards lowered the tax charge by \$30 million, \$34 million, and \$26 million in 2004, 2003 and 2002, respectively.

#### 7. Earnings per share (EPS)

Basic earnings per share is calculated by dividing the net income attributable to shareholders by the weighted average number of shares outstanding during the year, excluding from the issued shares the average number of shares purchased by the Group and held as treasury shares.

	2004	2003	2002
Net income (\$ millions)	5,767 2,447,954,717	- ,	4,725 2,515,311,685
Basic earnings per share (\$)	2.36	2.03	1.88

For the diluted earnings per share the weighted average number of shares outstanding is adjusted to assume conversion of all potentially dilutive shares.

### 7. Earnings per share (EPS) (Continued)

The diluted EPS calculation takes into account all potential dilutions to the earnings per share arising from options on Novartis shares.

	2004	2003	2002
Net income (\$ millions) Elimination of interest expense on convertible debt	5,767	5,016	4,725
(net of tax effect)			2
Net income used to determine diluted earnings per			
share	5,767	5,016	4,727
Weighted average number of shares outstanding	2,447,954,717	2,473,522,565	2,515,311,685
Call options on Novartis shares		27,446,092	54,891,036
Adjustment for dilutive share options	11,917,258	4,346,940	2,264,236
Weighted average number of shares for diluted			
earnings per share	2,459,871,975	2,505,315,597	2,572,466,957
Diluted earnings per share (\$)	2.34	2.00	1.84

Share equivalents of 13.0 million (2003: 16.4 million; 2002: 16.2 million) were excluded from the calculation of diluted earnings per share as they were not dilutive.

### 8. Property, plant & equipment movements

	Land	Buildings	Machinery	Plant under Construction and other equipment	2004	2003
			(\$ n	nillions)		
Cost						
January 1	367	5,247	7,909	1,370	14,893	12,670
Consolidation changes	1	10	19		30	
Reclassifications <sup>(1)</sup>	4	404	583	(991)		(237)
Additions	13	94	250	912	1,269	1,329
Disposals	(5)	(102)	(308)	(58)	(473)	(284)
Translation effects	23	376	598	130	1,127	1,415
December 31	403	6,029	9,051	1,363	16,846	14,893
Accumulated depreciation						
January 1	(1)	(2,544)	(4,751)		(7,296)	(6,349)
Consolidation changes			(1)		(1)	
Reclassifications <sup>(1)</sup>						334
Depreciation charge		(186)	(594)		(780)	(737)
Depreciation on disposals		82	262		344	188
Impairment charge		(4)	(12)		(16)	(31)
Translation effects	(1)	(208)	(391)		(600)	(701)
December 31	(2)	(2,860)	(5,487)		(8,349)	(7,296)
Net book value—						
December 31	401	3,169	3,564	1,363	8,497	7,597
Net book value of property, plant & equipment under finance lease contracts					132	135
Commitments for numbers of						
Commitments for purchases of property, plant & equipment					325	209

<sup>(1)</sup> Reclassifications between various asset categories as a result of recording final acquisition balance sheets or completion of plant under construction.

#### 9. Intangible asset movements

	Goodwill	Research & Development	Product and marketing rights	Trademarks (\$ millions)	Software	Other intangibles	2004	2003
Cost				(¢ mmons)				
January 1	2,097		3,578	441	122	615	6,853	6,144
Consolidation								
changes		139	158	104		90	491	24
Reclassifications <sup>(1)</sup> .	6		1	(8)	1			(21)
Additions	535		15	4	16	148	718	521
Disposals	(20)		(29)	(5)	(10)	(49)	(113)	(316)
Translation effects	121	12	235	12	7	20	407	501
<b>December 31</b>	2,739	151	3,958	548	136	824	8,356	6,853
Accumulated amortization								
January 1	(620)		(981)	(153)	(96)	(295)	(2, 145)	(1,749)
Reclassifications <sup>(1)</sup> .				1		(1)	.,,,,	(2)
Amortization charge	(108)		(230)	(43)	(18)	(57)	(456)	(410)
Disposals	7		28	5	7	48	<u>95</u>	271
Impairment charge .	(75)		(12)				(87)	(105)
Translation effects	(44)		(69)	(4)	(5)	(12)	(134)	(150)
December 31	(840)		(1,264)	(194)	(112)	(317)	(2,727)	(2,145)
Net book value—								
<b>December 31</b>	1,899	151	2,694	354	24	507	5,629	4,708

<sup>(1)</sup> Reclassifications between various asset categories as a result of recording final acquisition balance sheets.

In 2004, impairment charges of \$87 million were recorded, principally relating to the valuation of Sandoz activities in Germany due to the effects of competitive pressures on pricing.

In 2003, impairment charges of \$105 million were recorded, principally relating to loss of market share which in the near future, was considered to be difficult to regain of the Sandoz activities in Germany; the divestment of Genetic Therapy Inc., US, a Pharmaceuticals Division research activity, to Cell Genesys Inc., US, and adjustments to CIBA Vision Business Unit intangibles related to the planned disposal of the refractive surgery activities.

#### 10. Investments in associated companies

Novartis has the following significant investments in associated companies which are accounted for by using the equity method:

		Balance leet val			tax inc ment e	
	2004	2003	2002	2004	2003	2002
			(\$ mill	ions)		
Roche Holding AG, Switzerland	6,234	5,662	5,462	97	(354)	(116)
Chiron Corporation, USA	1,143	1,118	996	33	134	107
Others	73	68	25	12	20	2
Total	7,450	6,848	6,483	142	<u>(200</u> )	(7)

The accounting standards of the Group's associated companies are adjusted to IFRS in cases where IFRS is not already used.

Due to the various estimates that have been made in applying the equity method accounting treatment for Roche Holding AG ("Roche") and Chiron Corporation ("Chiron"), adjustments may be necessary in succeeding years as more financial and other information becomes publicly available.

#### **Roche Holding AG**

The Group's holding in Roche voting shares was 33.3% at December 31, 2004 and 2003. This investment represents 6.3% of the total outstanding voting and non-voting equity instruments. In order to apply the equity method of accounting, independent appraisers have been used to estimate the fair value of Roche so as to determine the Novartis share of property, plant & equipment and intangible assets and the amount of the residual goodwill at the time of acquisition. The purchase price allocations were made on publicly available information at the time of acquisition of the shares.

The purchase price allocation is as follows:

	(\$ millions)
Identified intangible assets	4,161
Other net assets	104
Residual goodwill	2,971
Total purchase price	7,236
Net income effect—2004	27
Other accumulated equity adjustments	(1,029)
December 31, 2004 balance sheet value	6,234

The identified intangible assets principally relate to the value of currently marketed products and are being amortized straight-line over their estimated average useful life of 20 years. The residual goodwill is also being amortized on a straight-line basis over 20 years.

#### 10. Investments in associated companies (Continued)

The income statement effects from applying Novartis accounting policies to the Roche figures for 2004, 2003 and 2002 are as follows:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Depreciation and amortization of fair value adjustments to			
-property, plant & equipment and intangible assets	(166)	(143)	(129)
—goodwill	(136)	(127)	(91)
Prior year adjustment	30	(269)	(17)
Novartis share of estimated Roche current year			
consolidated pre-tax income	369	185	121
Pre-tax income statement effect	97	(354)	(116)
Deferred tax	(70)	(44)	23
Net income effect	27	(398)	(93)

The market value of the Novartis interest in Roche at December 31, 2004 was \$7.1 billion (Reuters symbol: RO.S).

#### **Chiron Corporation**

The Group's holding in the common stock of Chiron was 42.5% and 42.3% at December 31, 2004 and 2003, respectively. The recording of the results of the strategic interest in Chiron is based on the estimated Chiron equity at December 31 of each year. The amounts for Chiron incorporated into the Novartis consolidated financial statements take into account the effects stemming from differences in accounting policies between Novartis and Chiron (primarily Novartis' amortization over 10 years of in-process research and development arising on Chiron's acquisitions which are written off by Chiron in the year of acquisition).

The income statement effects from applying Novartis accounting policies to the Chiron figures for 2004, 2003 and 2002 figures are as follows:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Amortization of goodwill	(18)	(20)	(18)
Prior year adjustment	4	4	2
Novartis share of estimated Chiron current year			
consolidated pre-tax income	47	150	123
Pre-tax income statement effect	33	134	107
Deferred tax	(1)	(37)	(34)
Net income effect	32	97	73

The market value of the Novartis interest in Chiron at December 31, 2004 was \$2.6 billion (NASDAQ symbol: CHIR).

### 11. Deferred taxes

	2004	2003
	(\$ millions)	(\$ millions)
Assets associated with—employee benefit liabilities	658	481
—operating loss carryforwards	214	222
—inventories	791	957
—intangible assets	43	60
—other provisions and accruals	679	867
Less: valuation allowance	(196)	(186)
Deferred tax assets less valuation allowance	2,189	2,401
Liabilities associated with—property, plant & equipment depreciation	670	644
—prepaid pensions	1,016	983
	1,463	1,306
—inventories	235	205
Total liabilities	3,384	3,138
Net deferred tax liability	1,195	737

Movement in deferred tax asset valuation allowance:

	2004	2003	2002
January 1	\$ millions (186)	\$ millions (145)	\$ millions (58)
Additions	(45)	(44)	(101)
Utilization	35	3	33 (19)
December 31	(196)	(186)	(145)

A reversal of the valuation allowance could occur when circumstances make the realization of deferred tax assets probable. This would result in a decrease in the Group's effective tax rate.

At December 31, 2004 unremitted earnings of \$30 billion (2003: \$27 billion) have been retained by subsidiary companies for reinvestment. No provision is made for income taxes that would be payable upon the distribution of such earnings. If the earnings were remitted, an income tax charge could result based on the tax statutes currently in effect.

	2004	2003
	(\$ millions)	(\$ millions)
Temporary differences on which no deferred tax has been provided as they are permanent in nature related to:		
—investments in subsidiaries	(934)	775
—goodwill from acquisitions	1,121	995

### 12. Financial and other assets

	2004	2003
	(\$ millions)	(\$ millions)
Other investments and long-term loans	1,756	1,514
Prepaid benefit cost	4,337	3,976
Total	6,093	5,490

Other investments are valued at market value.

During 2004, \$35 million (2003: \$80 million; 2002: \$64 million) of unrealized losses on available-for-sale investments and \$14 million (2003: \$nil million; 2002: \$nil million) on other participations were considered to be other than temporary and were charged to the income statement.

#### 13. Inventories

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Raw material, consumables	546	531	498
Finished products	3,012	2,815	2,465
Total inventories	3,558	3,346	2,963

Movement in inventory write-downs deducted from inventory categories:

	2004	2003	2002
January 1	(\$ millions) (238)	(\$ millions) (252)	(\$ millions) (219)
Additions	(266)	(196)	(288)
Utilization	273	247	260
Translation effects	(29)	(37)	(5)
December 31	<u>(260)</u>	(238)	(252)

#### 14. Trade accounts receivable

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Total	5,102	4,603	3,915
Provision for doubtful receivables	(251)	(227)	(218)
Total trade accounts receivable, net	4,851	4,376	3,697

#### 14. Trade accounts receivable (Continued)

Movement in provision for doubtful receivables:

	2004	2003	2002
January 1	(\$ millions) (227)	(\$ millions) (218)	(\$ millions) (175)
Additions	(186)	(89)	(114)
Utilization	176	98	78
Translation effects	(14)	(18)	(7)
December 31	(251)	(227)	(218)

#### 15. Other current assets

	2004	2003	
	(\$ millions)	(\$ millions)	
Withholding tax recoverable		257	
Gerber Life insurance receivables		149	
Prepaid expenses —third parties	268	183	
—associated companies	3	5	
Other receivables —third party	1,086	688	
-associated companies		10	
Total other current assets	1,609	1,292	

#### 16. Marketable securities and derivative financial instruments

#### Market risk

The Group is exposed to market risk, primarily related to foreign exchange, interest rates and market value of the investment of liquid funds. Management actively monitors these exposures. To manage the volatility relating to these exposures the Group enters into a variety of derivative financial instruments. The Group's objective is to reduce, where it is deemed appropriate to do so, fluctuations in earnings and cash flows associated with changes in interest rates, foreign currency rates and market rates of investment of liquid funds and of the currency exposure of certain net investments in foreign subsidiaries. It is the Group's policy and practice to use derivative financial instruments to manage exposures and to enhance the yield on the investment of liquid funds. The Group does not enter into any financial transaction containing a risk that cannot be quantified at the time the transaction is concluded; i.e. it does not sell short assets it does not have, or does not know it will have, in the future. The Group only sells existing assets or hedges transactions and future transactions (in the case of anticipatory hedges) it knows it will have in the future based on past experience. In the case of liquid funds it writes options on assets it has, or on positions it wants to acquire, and for which it has the required liquidity. The Group therefore expects that any loss in value for these instruments generally would be offset by increases in the value of the hedged transactions.

#### 16. Marketable securities and derivative financial instruments (Continued)

#### (a) Foreign exchange rates

The Group uses the US dollar as its reporting currency and is therefore exposed to foreign exchange movements, primarily in European, Japanese, other Asian and Latin American currencies. Consequently, it enters into various contracts which change in value as foreign exchange rates change, to preserve the value of assets, commitments and anticipated transactions. The Group uses forward contracts and foreign currency option contracts to hedge certain anticipated foreign currency revenues and the net investment in certain foreign subsidiaries.

#### (b) Commodities

The Group has only a very limited exposure to price risk related to anticipated purchases of certain commodities used as raw materials by the Group's businesses. A change in those prices may alter the gross margin of a specific business, but generally by not more than 10% of that margin and is thus within the Group's risk management tolerance level. Accordingly, the Group does not enter into commodity future, forward and option contracts to manage fluctuations in prices of anticipated purchases.

#### (c) Interest rates

The Group manages its exposure to interest rate risk by changing the proportion of fixed rate debt and variable rate debt in its total debt portfolio. To manage this mix the Group may enter into interest rate swap agreements, in which it exchanges the periodic payments, based on a notional amount and agreed upon fixed and variable interest rates. Use of the above-mentioned derivative financial instruments has not had a material impact on the Group's financial position at December 31, 2004 and 2003 or the Group's results of operations for the years ended December 31, 2004, 2003 and 2002.

#### **Counterparty risk**

Counterparty risk encompasses issuer risk on marketable securities, settlement risk on derivative and money market contracts and credit risk on cash and time deposits. Issuer risk is minimized by only buying securities which are at least AA rated. Settlement and credit risk is reduced by the policy of entering into transactions with counterparties that are usually at least AA rated banks or financial institutions. Exposure to these risks is closely monitored and kept within predetermined parameters.

The Group does not expect any losses from non-performance by these counterparties and does not have any significant grouping of exposures to financial sector or country risk.

#### **Derivative financial instruments**

The following tables show the contract or underlying principal amounts and fair values of derivative financial instruments analyzed by type of contract at December 31, 2004 and 2003. Contract or underlying principal amounts indicate the volume of business outstanding at the balance sheet date and do not

### 16. Marketable securities and derivative financial instruments (Continued)

represent amounts at risk. The fair values are determined by the markets or standard pricing models at December 31, 2004 and 2003.

	under prin	Contract or underlying principal amount		Positive fair values		Negative fair values		
Derivative financial instruments	2004	2003	2004	2003	2004	2003		
		(\$ millions)						
Currency related instruments Forward foreign exchange rate contracts Over the counter currency options	5,771 3,987	5,470 4,016	65 6	360 34	(281) (3)	(398) (29)		
Cross currency swaps	1,226	1,123	296	223	(-)			
Total of currency related instruments	10,984	10,609	367	617	(284)	(427)		
Interest rate related instruments								
Interest rate swaps	3,820	3,826	11	12	(7)	(10)		
Forward rate agreements	9,219	6,194	6	2	(6)	(3)		
Interest rate options	100	520				(1)		
Total of interest rate related instruments	13,139	10,540	17	14	(13)	(14)		
Options on equity securities	268	1,242	15	68		(58)		
Total derivative financial instruments included in marketable								
securities and in short-term financial debt	24,391	22,391	<u>399</u>	<u>699</u>	<u>(297</u> )	<u>(499</u> )		
Currency related instruments included in other current assets and liabilities								
Forward foreign exchange rate contracts		1,946		23		(34)		
Over the counter currency options		2						
Total currency related instruments included in other current assets and liabilities		1,948		23		(34)		
Total derivative financial instruments	24,391	24,339	399	722	(297)	(533)		

#### 16. Marketable securities and derivative financial instruments (Continued)

The contract or underlying principal amount of derivative financial instruments at December 31, 2004 and 2003 are set forth by currency in the table below.

	CHF	EUR	\$	JPY	Other currencies	Total 2004	Total 2003
				(\$ mi	llions)		
Currency related instruments							
Forward foreign exchange rate contracts	2	970	3,725	959	115	5,771	7,416
Over the counter currency options		544	509	145	2,789	3,987	4,018
Cross currency swaps		1,226				1,226	1,123
Currency related derivatives	2	2,740	4,234	1,104	2,904	10,984	12,557
Interest rate related instruments							
Interest rate swaps	441	2,179	1,200			3,820	3,826
Forward rate agreements		5,719	3,500			9,219	6,194
Interest rate options			100			100	520
Interest rate related derivatives	441	7,898	4,800			13,139	10,540
Options on equity securities		58	210			268	1,242
Total derivative financial instruments	443	10,696	9,244	1,104	2,904	24,391	24,339

Derivative financial instruments effective for hedge accounting purposes

	Contract or underlying principal amount	Fair values
	2003	2003
	(\$ million	ns)
Anticipated transaction hedges		
Forward foreign exchange rate contracts	3,167	25
Over the counter currency options	2	
Total of anticipated transaction hedges effective for hedge accounting		
purposes	3,169	25

At December 31, 2004 there were no derivative financial instruments effective for hedge accounting purposes.

#### 16. Marketable securities and derivative financial instruments (Continued)

#### Marketable securities, time deposits and derivative financial instruments

	2004	2003
	(\$ millions)	(\$ millions)
Available-for-sale marketable securities		
Equity securities	435	1,277
Debt securities	6,188	4,857
Total available-for-sale marketable securities	6,623	6,134
Time deposits with remaining maturity more than 90 days	1,353	651
Derivative financial instruments	399	699
Accrued interest on derivative financial instruments	26	42
Accrued interest on debt securities	109	87
Total marketable securities, time deposits and derivative financial		
instruments	8,510	7,613

During 2004, unrealized losses of \$66 million on available-for-sale marketable securities were considered to be other than temporary and charged to the income statement (2003: \$66 million; 2002: nil).

### 17. Details of shares and share capital movements

		Number	of outstanding	shares <sup>(1)</sup>	
	December 31, 2002	Movement in year	December 31, 2003	Movement in year	December 31, 2004
Total Novartis shares	2,824,150,000	(22,680,000)	2,801,470,000	(24,260,000)	2,777,210,000
Treasury shares Shares reserved for employee					
share ownership plans	41,569,718		41,569,718		41,569,718
Shares reserved for call options .	54,901,962	(54,901,962)			
Unreserved treasury shares	252,707,701	39,423,921	292,131,622	16,698,584	308,830,206
Total treasury shares	349,179,381	(15,478,041)	333,701,340	16,698,584	350,399,924
Total outstanding shares	2,474,970,619	(7,201,959)	2,467,768,660	(40,958,584)	2,426,810,076
			(\$ millions)		
Share capital	1,025	(8)	1,017	(9)	1,008
Treasury shares	(127)	6	(121)	(6)	(127)
Outstanding share capital	898	(2)	896	(15)	881

<sup>(1)</sup> All shares are registered, authorized, issued and fully paid. All are voting shares and, except for 291,462,603 treasury shares, are dividend bearing.

## 18. Long-term financial debts

Straight bonds          Liabilities to banks and other financial institutions <sup>(1)</sup> Finance lease obligations          Total (including current portion of long-term debt)          Less current portion of long-term debt	<b>2004</b> (\$ millions) 3,185 114 <u>117</u> <b>3,416</b> (680)	2003 (\$ millions) 2,972 142 122 3,236 (45)
Total long-term debts	2,736	3,191
Straight bonds USD 6.625% Euro Medium Term Note 1995/2005 of Novartis Corporation, Florham Park, New Jersey, US	300	300
USD 6.625% Euro Medium Term Note 1995/2005 of Novartis Corporation, Florham Park, New Jersey, US USD	250	250
9.0% bonds 2006 of Gerber Products Company, Fremont, Michigan, US EUR	35	35
4.0% EUR 900 million bond 2001/2006 of Novartis Securities Investment Ltd., Hamilton, Bermuda <sup>(2)</sup> EUR	1,228	1,127
3.75% EUR 1 billion bond 2002/2007 of Novartis Securities Investment         Ltd., Hamilton, Bermuda         Total straight bonds	1,372 3,185	1,260 2,972

<sup>(1)</sup> Average interest rate 3.4%. (2003: 3.4%).

<sup>(2)</sup> Swapped into Swiss francs in 2002

#### 18. Long-term financial debts (Continued)

	2004	2003
	(\$ millions)	(\$ millions)
Breakdown by maturity		
2004		45
2005	680	677
2006	1,288	1,178
2007	1,388	1,274
2008	20	23
2009	16	39
Thereafter	24	
Total	3,416	3,236
Breakdown by currency		
USD	707	719
EUR	1,474	1,382
CHF	1,228	1,127
Others	7	8
Total	3,416	3,236

Fair value comparison

	2004 Balance	2004	2003 Balance	2003
	sheet	Fair values	sheet	Fair values
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Straight bonds	3,185	3,272	2,972	3,057
Others	231	231	264	264
Total	3,416	3,503	3,236	3,321

	2004	2003
Collateralized long-term debts and pledged assets	(\$ millions)	(\$ millions)
Total amount of collateralized long-term financial debts	20	50
Total net book value of property, plant & equipment pledged as collateral		
for long-term financial debts	88	101

The percentage of fixed rate debt to total financial debt was 47% and 51% at December 31, 2004 and 2003, respectively.

The financial debts, including short-term financial debts, contain only general default covenants. The Group is in compliance with these covenants.

#### 19. Provisions and other long-term liabilities

	2004	2003
	(\$ millions)	(\$ millions)
Accrued liability for employee benefits:		
—defined benefit pension plans	988	930
—other long-term employee benefits and deferred compensation	324	183
	495	460
Liabilities for insurance activities	862	766
Environmental provisions	202	177
Provision for legal and product liability settlements	297	335
Deferred purchase consideration		4
Other provisions	182	294
Total	3,350	3,149

#### a) Environmental matters

Novartis has provisions in respect of environmental remediation costs in accordance with the accounting policy described in Note 1. The accrual recorded at December 31, 2004 consists of \$111 million (2003: \$84 million) provided for remediation at third party sites and \$107 million (2003: \$95 million) for remediation of owned facilities. In the US, Novartis has been named under federal legislation (the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended) as a potentially responsible party ("PRP") in respect to certain sites. Novartis actively participates in, or monitors, the clean-up activities at the sites in which it is a PRP. The estimated reserve takes into consideration the number of other PRPs at each site and the identity and financial position of such parties in light of the joint and several nature of the liability.

The requirement in the future for Novartis ultimately to take action to correct the effects on the environment of prior disposal or release of chemical substances by Novartis or other parties, and its costs, pursuant to environmental laws and regulations, is inherently difficult to estimate. The material components of the environmental provisions consist of costs to fully clean and refurbish contaminated sites and to treat and contain contamination at sites where the environmental exposure is less severe. The Novartis future remediation expenses are affected by a number of uncertainties which include, but are not limited to, the method and extent of remediation, the percentage of material attributable to Novartis at the remediation sites relative to that attributable to other parties, and the financial capabilities of the other potentially responsible parties.

In connection with the 1997 spin-off of CIBA Specialty Chemicals AG ("CSC") from Novartis AG, a Novartis affiliate has agreed to reimburse CSC 50% of the costs: (i) associated with environmental liabilities arising in the US from the operations of the specialty chemicals business of the US affiliates of the former Ciba-Geigy AG, and (ii) which exceed reserves agreed between that affiliate and CSC. The reimbursement obligations are not subject to any time or amount limits but could terminate for certain liabilities in the US upon the occurrence of certain contingencies which include the merger of CSC or the sale of its assets.

Novartis believes that its total reserves for environmental matters are adequate based upon currently available information, however, given the inherent difficulties in estimating liabilities in this area, it cannot be guaranteed that additional costs will not be incurred beyond the amounts accrued. The effect of

#### 19. Provisions and other long-term liabilities (Continued)

resolution of environmental matters on results of operations cannot be predicted due to uncertainty concerning both the amount and the timing of future expenditures and the results of future operations. Management believes that such additional amounts, if any, would not be material to the Group's financial condition but could be material to the results of operations in a given period.

The following table shows the movements in the environmental liability provisions during 2004, 2003 and 2002:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
January 1	179	163	136
Cash payments	(9)	(4)	(2)
Releases	(4)	(18)	(8)
Additions	41	25	16
Translation effect, net	11	13	21
December 31	218	179	163
Less short-term liability	(16)	(2)	(2)
Long-term liability at December 31	202	177	161

#### b) Legal and product liabilities

#### Litigation

A number of Group companies are the subject of litigation arising out of the normal conduct of their business, as a result of which claims could be made against them which, in whole or in part, might not be covered by insurance. Provisions are established for the gross amount of any probable claim that can be reasonably estimated. Insurance receivables are recorded only in respect of amounts that are virtually certain to be recovered. In the opinion of Group management, however, the outcome of the actions if any, would not be material to the Novartis financial condition but could be material to the Novartis results of operations in a given period.

#### Average Wholesale Price Litigation

Claims have been brought against various US pharmaceutical companies, including Novartis affiliates alleging that they have fraudulently overstated the Average Wholesale Price (AWP) and "best price", which are used by the US government to calculate, respectively, Medicare and Medicaid reimbursements. Novartis affiliates have been named in a number of these cases. Discovery is in process against certain defendants in these cases, but not yet against Group affiliates. Novartis affiliates have also voluntarily participated in an ongoing Congressional inquiry on the subject of AWP and pharmaceutical pricing.

#### **Canadian Importation Cases**

Novartis affiliates, along with various other pharmaceutical companies, are parties to suits alleging a conspiracy among pharmaceutical companies to keep prices of pharmaceuticals in the US artificially high by blocking imports of Canadian drugs to US consumers. Pretrial motion practice is underway in these cases.

#### 19. Provisions and other long-term liabilities (Continued)

#### Chiron

Novartis owns approximately 42.5% of the shares of Chiron Corporation. Chiron and its officers and directors are currently the subject of a number of lawsuits and government investigations which include allegations of, among other things, breaches of the securities laws and of fiduciary duties, arising out of Chiron's inability to deliver its Fluvirin<sup>®</sup> influenza vaccine to the US market for the 2004/05 flu season. Novartis AG has been named as a defendant in three of these cases. All of these cases are in the earliest stages.

#### **HRT** Litigation

A Novartis affiliate is a defendant, along with various other pharmaceutical companies, in approximately 60 cases brought by people claiming to have been injured by hormone replacement therapy (HRT) products. Discovery is underway in these cases.

#### **Pharmaceutical Antitrust Litigation**

A Novartis affiliate along with numerous other prescription drug manufacturers, is a co-defendant in various actions brought by certain US retail pharmacies, alleging antitrust and pricing violations. Pretrial motion practice is underway.

#### PPA

Novartis affiliates are parties to approximately 250 lawsuits in the US brought by people claiming to have been injured by products containing phenylpropanolamine (PPA) sold by certain of those affiliates. These cases are in various stages of litigation with Novartis having achieved victories in the first three lawsuits to have gone to trial. However, more trials are expected to follow. There can be no guarantee that the affiliates' initial successes will be repeated or sustained in the event of an appeal.

#### SMON (Subacute Myelo Optico Neuropathy)

In 1996 an affiliate of Ciba-Geigy, one of the predecessor companies of Novartis, together with two other pharmaceutical companies, settled certain product liability issues related to sales of its product Clioquinol in Japan. Under the settlement, a Novartis affiliate is required to pay certain future health care costs of the claimants.

#### Terazosin

A Sandoz affiliate is a defendant in a number of lawsuits in the US claiming injuries and damages allegedly arising out of violation of antitrust laws in the settlement, by the affiliate and Abbott Pharmaceuticals, of a contentious patent litigation involving Abbott's Hytrin<sup>®</sup> and the Sandoz generic equivalent product. The affiliate has a judgment sharing agreement with Abbott that caps its liability. In addition, in one of the proceedings, the affiliate was successful in overturning on appeal trial court decisions that the settlement of the litigation was *per se* unlawful and certifying a plaintiff's class. The case has been remanded to the trial court for further proceedings.

#### 19. Provisions and other long-term liabilities (Continued)

Novartis believes that its affiliates have meritorious defenses in these cases, and they are vigorously defending each of them.

Novartis maintains property damage, business interruption, product liability and other insurance policies with third parties, covering claims on a worldwide basis. Novartis believes that its insurance coverage and provisions are reasonable and prudent in light of its business and the risks to which it is subject. However, events may occur which in whole or in part, might not be covered by third party insurance or the provisions that Novartis have put in place. This is particularly true with respect to product liability claims where other pharmaceutical companies have faced large losses, making third party insurance coverage increasingly difficult to obtain. As a result, while no such losses are presently expected, there can be no guarantee that Novartis will not also face a loss which far exceeds available insurance or provisions.

#### Investigations

From time to time, the Group's affiliates may be the subject of government investigations arising out of the normal conduct of their business. Consistent with the Novartis Code of Conduct and policies regarding compliance with law, it is the Group's policy to cooperate with such investigations.

#### US enteral pump market

A Novartis Medical Nutrition affiliate in the US is a subject of an investigation by the US Department of Justice regarding marketing and pricing practices in the US enteral pump market, including whether certain federal criminal statutes have been violated. Novartis is in the process of negotiating a possible settlement of that investigation.

#### **UK generics**

One of the Group's UK Sandoz affiliates, along with other generic drug companies, is a subject of an investigation by the UK Serious Fraud Office ("SFO") to determine whether its marketing practices during the period prior to its acquisition by Novartis violated criminal or competition laws. The affiliate is cooperating with the SFO's investigation.

Novartis believes that its total provisions for legal and product liability matters are adequate based upon currently available information, however, given the inherent difficulties in estimating liabilities, it cannot be guaranteed that additional costs will not be incurred beyond the amounts accrued. Management believes that such additional amounts, if any, would not be material to the Group's financial condition but could be material to the results of operations in a given period.

#### 19. Provisions and other long-term liabilities (Continued)

The following table shows the movements in the legal and product liability provisions during 2004, 2003 and 2002:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
January 1	471	<b>420</b> 26	316
Cash payments	(141)	(152)	(60)
Releases   Additions	(71) 274	(158) 317	(19) 160
Translation effect, net	14	18	23
December 31	<b>547</b> (250)	<b>471</b> (136)	<b>420</b> (166)
Long-term liability at December 31	297	335	254

#### 20. Short-term financial debts

	2004	2003
	(\$ millions)	(\$ millions)
Interest bearing employee accounts	1,012	926
Other bank and financial debt	1,049	660
Commercial paper	372	649
Current portion of long-term financial debt	680	45
Financial obligation for repurchase agreement	709	
Fair value of derivative financial instruments	297	499
Total	4,119	2,779

The balance sheet values of short-term financial debt, other than the current portion of long-term financial debts, approximates to the estimated fair value due to the short-term nature of these instruments.

The weighted average interest rate on the bank and other financial debt including employee accounts was 2.5% and 3.1% in 2004 and 2003, respectively.

#### 21. Other short-term liabilities

	2004	2003
	(\$ millions)	(\$ millions)
Income and other taxes	703	872
Restructuring liabilities	30	43
Accrued expenses for goods and services received but not invoiced	1,442	1,521
Accruals for royalties	162	139
Accrued rebates for Medicaid and Managed Care	454	426
Potential claims from insurance activities	171	149
Accruals for compensation and benefits including social security and		
pension funds	771	654
Environmental liabilities	16	2
Deferred income relating to government grants	13	14
Goods returned and commission accruals	240	239
Provision for product liability and other legal cases	250	136
Other payables	687	681
Total	4,939	4,876

#### Restructuring charges

In October 2002, charges of \$20 million were incurred in conjunction with the divestment of the Food & Beverage business to Associated British Foods plc (ABF). The charges comprised employee termination costs of \$8 million and other third party costs of \$12 million. 45 employees not transferred to ABF were identified in the original plan, all but 4 of them have now left the Group. These associates are fulfilling an interim service level agreement with the new owners and are expected to leave in 2005. All other significant actions associated with the plan were completed during 2004.

In December 2002, provision was made for charges of \$28 million in conjunction with the re-organization of the Health Food and Slimming and Sports Nutrition businesses into a stand-alone unit called Nutrition & Santé. The charges comprised employee termination costs of \$17 million and other third party costs of \$11 million. 120 employees were identified in the original plan of whom 6 remained employed by the Group as at December 31, 2004, but all of whom are expected to leave in 2005. All other significant actions of this plan were completed in 2004.

In December 2002 charges of \$10 million were incurred in conjunction with the plan to restructure the OTC business. The charges comprised employee termination costs of \$9 million and other third party costs of \$1 million. 90 positions were impacted by the restructuring all of whom have now left the Group. All other actions of this plan were completed in 2004.

In November 2004 charges of \$10 million were incurred in conjunction with the plan to restructure the Pharma site at Huningue, France. The charges comprised employee termination costs of \$10 million. 40 employees are impacted by the restructuring plan.

In December 2004 charges of \$37 million were incurred in conjunction with various plans to restructure the Sandoz industrial operations in a number of different sites to reinforce the competitiveness of its business. The charges comprised employee termination costs of \$19 million, impairment of property,

#### 21. Other short-term liabilities (Continued)

plant & equipment of \$16 million and other third party costs of \$2 million. In total, 363 employees are impacted by the various restructuring plans.

The releases to income in 2004, 2003 and 2002 of \$6 million, \$12 million and \$23 million respectively were mainly due to settlement of liabilities at lower amounts than originally anticipated.

Property, plant & equipment impairments related to restructuring are determined based on the review of the carrying values of property, plant & equipment. Write-downs are recorded for property, plant & equipment impaired or related to activities to be restructured, divested or abandoned. The provision is transferred to accumulated depreciation as the property, plant & equipment are restructured, divested or abandoned.

Other third party costs are mainly associated with lease and other obligations due to the abandonment of certain facilities.

	Employee termination <u>costs</u> (\$ millions)	Property, plant & equipment impairments (\$ milllions)	Other third party costs (\$ millions)	Total (\$ millions)
Balance at January 1, 2002	36	31	74	141
Cash payments	(21)		(58)	(79)
Releases	(6)	(12)	(5)	(23)
Additions	34		24	58
Non-income property, plant & equipment				
write-offs		(4)		(4)
Translation effect, net	3		2	5
Balance at December 31, 2002	46	15	37	98
Cash payments	(27)		(16)	(43)
Releases	(1)	(2)	(9)	(12)
Balance at December 31, 2003	18	13	12	43
Cash payments	(23)		(3)	(26)
Releases			(6)	(6)
Additions	29	16	2	47
Transfer to property, plant & equipment		(20)		(20)
or other balance sheet position		(29)	1	(29)
Translation effect, net				
Balance at December 31, 2004		_	<u> </u>	30

# 22. Cash flows arising from changes in working capital and other operating items included in operating cash flow

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Change in inventories Change in trade accounts receivable, net current assets	23	(78)	(275)
other operating items	(130)	297	49
Change in trade accounts payable	239	238	74
Total	132	457	(152)

#### 23. Acquisitions and divestments of businesses

#### a) Cash flow arising from major acquisitions and divestments

The following is a summary of the cash flow impact of the major divestments and acquisitions of businesses:

	2004 Acquisitions	2004 Divestments	2003 Acquisitions	2002 Acquisitions	2002 Divestments
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Property, plant & equipment Currently marketed products including	(29)	3	(1)	(165)	61
trademarks	(262)		(24)	(28)	5
In-process research and development	(139)				
Other intellectual property	(90)				
Financial assets	(5)				
Inventories Trade accounts receivable and other	(69)	4	(1)	(125)	19
current assets	(20)		(1)	(106)	33
term deposits Long-term and short-term debt to third	(6)			(103)	20
parties	8	(2)		5	(21)
Bank borrowing	86				
Trade accounts payable and other					
liabilities including deferred taxes	109	<u>(3</u> )	36	133	21
Net identifiable assets acquired/divested .	(417)	2	9	(389)	138
Acquired/divested liquidity	6		18	103	(20)
Sub-total	(411)	2	27	(286)	118
Refinancing of acquired debt	(86)				
Goodwill	(535)		(303)	(618)	
Divestment gains or losses		(1)			133
Amount settled in treasury shares				78	
Translation effects		_	4	33	
Net Cash Flow	(1,032)	1	(272)	(793)	251

#### 23. Acquisitions and divestments of businesses (Continued)

Note 2 provides further information regarding changes in the consolidation scope. All acquisitions were for cash, except in 2002 when an amount equivalent to \$78 million was settled in Novartis ADSs.

## b) Assets and liabilities arising from the 2004 acquisitions

	Fair value	Revaluation due to purchase accounting	Acquiree's carrying amount
	(\$ millions)	(\$ millions)	(\$ millions)
Property, plant & equipment	29	2	27
Currently marketed products including trademarks	262	137	125
In-process research and development	139	138	1
Other intellectual property	90	90	
Financial assets	5		5
Inventories	69	18	51
Trade accounts receivable and other current assets	20	1	19
Marketable securities, cash and short-term deposits	6		6
Long-term and short-term debt to third parties	(8)		(8)
Bank borrowing	(86)		(86)
Trade accounts payable and other liabilities including deferred taxes .	(109)	(74)	(35)
Net identifiable assets acquired	417	312	105
Less acquired liquidity	(6)		
Refinancing of acquired debt	86		
Goodwill	535		
Total cash flow from acquisition of businesses in 2004	1,032		

Professional fees and related expenses incurred for the acquisitions amount to \$12 million.

### 24. Changes in consolidated equity

(a) The 2004, 2003 and 2002 changes in the fair value of financial instruments not recorded in the income statement and transfers to the income statement consist of the following:

	Fair value adjustments to marketable securities	Fair value of deferred cash flow hedges	Total
	(\$ millions)	(\$ millions)	(\$ millions)
Fair value adjustments at January 1, 2002	656	(10)	646
Changes in fair value:			
—available-for-sale marketable securities	(494)		(494)
—cash flow hedges	(2.1.1)	144	144
	(344)		(344)
Realized gains or losses transferred to the income			
statement: —marketable securities sold	(174)		(174)
-derivative financial instruments	(174)	(88)	(174) (88)
-other financial assets sold	(8)	(00)	(8)
Impaired other financial assets	64		64
Reclassification in equity <sup>(1)</sup>	(98)	79	(19)
Deferred tax on above	99	(12)	87
Fair value adjustments at December 31, 2002	(299)	113	(186)
Changes in fair value: —available-for-sale marketable securities	146		146
-cash flow hedges	140	26	26
-cash how hedges	21	20	20
	41		41
Realized net losses transferred to the income statement:	71		71
-marketable securities sold	92		92
—derivative financial instruments	~=	(165)	(165)
-other financial assets sold	1	(100)	(100)
Impaired marketable securities and other financial assets .	146		146
Deferred tax on above	(74)	33	(41)
Fair value adjustments at December 31, 2003	74	7	81
Changes in fair value:	/4	7	01
-available-for-sale marketable securities	22		22
-other financial assets	19		19
-associated companies' equity movements	26		26
Realized net losses transferred to the income statement:			
—marketable securities sold	185		185
—derivative financial instruments		(25)	(25)
	(7)		(7)
Impaired marketable securities and other financial assets .	101		101
Deferred tax on above	(23)	(2)	(25)
Fair value adjustments at December 31, 2004	397	(20)	377

<sup>(1)</sup> Transfer of \$98 million of unrealized gains to retained earnings due to fair value adjustments on Syngenta AG shares retained by the Group after the 2000 Novartis Agribusiness spin-off and transfer of \$79 million of translation losses in connection with hedges of the translation of net investments in foreign subsidiaries.

#### 24. Changes in consolidated equity (Continued)

- (b) The Group has investments in associated companies, principally Roche Holding AG and Chiron Corporation. The Group's share in movements in these companies' equity other than relating to net income, are allocated directly to the Group's consolidated statement of changes in equity.
- (c) Goodwill previously written-off against retained earnings, in accordance with IFRS in effect prior to 1995, has been transferred to the income statement as a reduction of a gain following the renegotiation in 2002 of the final purchase price of this 1994 transaction.
- (d) The Board of Directors proposes a dividend of CHF 1.05 per share for 2004 totaling \$2.2 billion for all dividend bearing shares (2003: CHF 1.00 per share amounting to \$2.0 billion which was paid in 2004; 2002: CHF 0.95 per share amounting to \$1.7 billion which was paid in 2003). The amount available for dividend distribution is based on the available distributable retained earnings of Novartis AG determined in accordance with the legal provisions of the Swiss Code of Obligations.
- (e) \$1.0 billion of shares were acquired during 2004 under the Group's third and \$0.7 billion under the Group's fourth share buy-back program on the second trading line. Overall in 2004, a total of 41 million shares have been repurchased for \$1.9 billion, which includes shares bought on the first trading line. In addition, in 2004, there was a \$10 million increase in equity due to a non-cash deferred tax credit on treasury share purchases. This resulted in a net reduction of the Group's consolidated equity of \$1.9 billion (2003: \$273 million; 2002 \$3.2 billion).
- (f) During December 2001, Novartis sold a total of 55 million ten-year call options (Low Exercise Price Options—"LEPOs") on Novartis shares, with an exercise price of CHF 0.01, to a third party. The Group received EUR 2.2 billion in proceeds (EUR 40 per LEPO). The Group accounted for the LEPOs as an increase in share premium at fair value less related issuance costs. Following changes in US GAAP and expected changes in IFRS rules, Novartis redeemed, in advance, these equity instruments on June 26, 2003.
- (g) During December 2001, Novartis sold a total of 55 million nine and ten-year put options on Novartis shares to a third party with an exercise price of EUR 51, the Group received EUR 0.6 billion in proceeds (EUR 11 per put option). The Group accounted for the option premium associated with the put options as an increase in share premium less related issuance costs. Following changes in US GAAP and expected changes in IFRS, Novartis redeemed, in advance, these equity instruments on June 26, 2003.
- (h) Pursuant to a resolution approved at the February 24, 2004 Annual General Meeting, 24.3 million shares with a nominal value of \$9 million were cancelled (2003: 22.7 million shares were cancelled with a nominal value of \$8 million).
- (i) As a result of the partial repayment of capital of a subsidiary in 2004 the Group has recycled \$301 million of cumulative translation differences into financial income.
- (j) Share premium has been increased by \$26 million to the required minimum under Swiss company law of 20% of the Novartis AG share capital.

#### 25. Employee benefits

#### a) Defined benefit plans

The Group has, apart from the legally required social security schemes, numerous independent pension and other post-employment benefit plans. For certain Group companies, however, no

#### 25. Employee benefits (Continued)

independent assets exist for the pension and other long-term employee benefit obligations. In these cases the related liability is included in the balance sheet.

Defined benefit pension plans cover the majority of the Group's employees. The defined benefit obligations and related assets of all major plans are reappraised annually by independent actuaries. Plan assets are recorded at fair values. The defined benefit obligation of unfunded pension plans was \$821 million at December 31, 2004 (2003: \$753 million).

The following is a summary of the status of the main funded and unfunded pension and other post-employment benefit plans at December 31, 2004 and 2003:

	Pensio	n plans	post-emp	her ployment t plans
	2004	2003	2004	2003
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Benefit obligation at beginning of the year	13,865	11,845	720	645
Service cost	351	285	24	19
Interest cost	580	559	42	40
Actuarial losses	1,401	695	91	85
Plan amendments	(41)	15	(8)	(31)
Foreign currency translation	1,204	1,256	3	2
Benefit payments	(872)	(790)	(44)	(40)
Benefit obligation at end of the year	16,488	13,865	828	720
Fair value of plan assets at beginning of the year	16,128	14,365		
Actual return on plan assets	738	916		
Foreign currency translation	1,417	1,506		
Employer contributions	207	92		
Employee contributions	52	39		
Plan amendments	(7)			
Benefit payments	(872)	(790)		
Fair value of plan assets at end of the year	17,663	16,128		
Funded Status	1,175	2,263	(828)	(720)
Unrecognized past service cost	6	6	(33)	(39)
Unrecognized net actuarial losses	2,168	777	366	299
Net asset/(liability) in the balance sheet $\ldots$	3,349	3,046	(495)	(460)

## 25. Employee benefits (Continued)

The movement in the net asset and the amounts recognized in the balance sheet were as follows:

	Pensio	n plans	employme	r post- ent benefit ans
	2004	2003	2004	2003
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Movement in net asset/ (liability)				
Net asset/(liability) in the balance sheet at				
beginning of the year	3,046	2,786	(460)	(421)
Net periodic benefit costs	(198)	(54)	(75)	(63)
Employer contributions/benefit payments	207	92	44	40
Past service cost arisen in the current year	(19)	(33)	8	4
Plan amendments, net	34	(15)	(8)	(31)
Foreign currency translation	279	270	(4)	11
Net asset/(liability) in the balance sheet at end of				
the year	3,349	3,046	( <b>495</b> )	(460)
Amounts recognized in the balance sheet				
Prepaid benefit cost	4,337	3,976		
Accrued benefit liability	(988)	(930)	(495)	(460)
Net asset/(liability) in the balance sheet $\ldots$	3,349	3,046	( <b>495</b> )	(460)

The net periodic benefit cost recorded in the income statement consisted of the following components:

	]	Pension plan	S		r post-employ benefit plans	
	2004	2003	2002	2004	2003	2002
	(\$ millions)	(\$ millions)				
Components of net periodic benefit cost						
Service cost	351	285	277	24	19	14
Interest cost	580	559	552	42	40	36
Expected returns on plan						
assets	(715)	(796)	(970)			
Employee contributions	(52)	(39)	(7)			
Recognized actuarial						
losses	53	72		23	8	
Recognized past service						
cost	(19)	(27)	9	(14)	(4)	4
Net periodic benefit cost .	198	54	(139)	75	63	54

#### 25. Employee benefits (Continued)

The principal actuarial weighted average assumptions used for calculating defined benefit plans and other post-employment benefits are as follows:

	Per	ision pl	ans		Other employ nefit pla	
	2004	2003	2002	2004	2003	2002
	%	%	%	%	%	%
Weighted average assumptions used to determine benefit obligations at the end of year						
Discount rate	3.8	4.3	4.5	5.8	6.3	6.8
Expected rate of salary increase	2.8	2.8	2.8			
Weighted average assumptions used to determine net periodic pension cost for the year ended						
Discount rate	4.3	4.6	4.5	5.8	6.3	6.8
Expected return on plan assets	4.5	5.6	6.1			
Expected rate of salary increase	2.1	2.8	2.8			

The weighted average asset allocation of funded defined benefit plans at December 31, 2004 was as follows:

	Pension plans		
	Long-term target	2004	2003
	%	%	%
Equity securities	15-40	25	22
Debt securities	45-70	58	59
Real estate	0-15	8	8
Cash and other investments	0-15	9	11
Total		100	100

Strategic pension plan asset allocations are determined by the objective to achieve an investment return which, together with the contributions paid, is sufficient to maintain reasonable control over the various funding risks of the plans. Based upon current market and economic environments, actual asset allocation may periodically deviate from policy targets as determined by the plan trustees and by the Novartis pension board.

#### 25. Employee benefits (Continued)

The expected future cash flows to be paid by the Group in respect of pension and other post-employment benefit plans at December 31, 2004 was as follows:

	Pension plans	Other post-employment
	(\$ millions)	(\$ millions)
Employer contributions		
2005 (estimated)	179	
Expected future benefit payments		
2005	1,004	44
2006	1,005	44
2007	1,021	46
2008	1,046	47
2009	1,061	49
2010–2014	5,483	268

The health care cost trend rate assumptions for other post-employment benefits are as follows:

Health care cost trend rate assumptions used		2003	2002
Health care cost trend rate assumed for next year	11.0%	9.0%	10.0%
Rate to which the cost trend rate is assumed to decline	4.8%	4.8%	4.8%
Year that the rate reaches the ultimate trend rate	2012	2012	2006

A one-percentage-point change in the assumed healthcare cost trend rates compared to those used for 2004 would have the following effects:

	1% point increase	1% point decrease
	(\$ millions)	(\$ millions)
Effects on total of service and interest cost components	9	(7)
Effect on post-employment benefit obligations	112	(93)

The number of Novartis AG shares held by pension and similar benefit funds at December 31, 2004 was 30.9 million shares with a market value of \$1.6 billion (2003: 31.5 million shares with a market value of \$1.3 billion). These funds sold 0.6 million Novartis AG shares during the year ended December 31, 2004 (2003: nil). The amount of dividends received on Novartis AG shares held as plan assets by these funds were \$25 million for the year ended December 31, 2004 (2003: \$22 million; 2002: \$22 million).

#### b) Defined contribution plans

In some Group companies employees are covered by defined contribution plans and other long-term employee benefits. The liability of the Group for these benefits is reported in other long-term employee benefits and deferred compensation and at December 31, 2004 amounts to \$324 million (2003: \$183 million). In 2004 contributions charged to the consolidated income statement for the defined contribution plans were \$94 million (2003: \$84 million; 2002: \$85 million).

#### 26. Employee share participation plans

Employee and management share participation plans can be separated into share option plans and share plans.

#### Share option plans

In 2004, the Board of Directors adopted the following modification to the Share Option Plans. Participants have the choice to receive their share option award in the form of share options, or restricted shares or in equal parts in share options and restricted shares. An exchange ratio of share options to shares is set by the Board. For 2004, four share options could be exchanged for one restricted share. Shares granted have a restriction period identical to the vesting period of the share options. Executives and employees participating in the Share Option Plans were granted 792 470 shares for the Novartis Share Option Plan and 1 439 567 shares for the Novartis US ADS Incentive Plan.

#### a) Novartis Share Option Plan

Under the current plan, tradable share options are granted annually as part of the remuneration of executives and other employees, as selected by the Board's Compensation Committee. In 2004, except for Switzerland the vesting period was changed for the 2004 grants only from a two-year vesting period to a three-year vesting period and the term was changed for all grants from nine years to ten years. Each option entitles the holder to acquire one Novartis AG share at a predetermined exercise price. In May 2001, the Novartis AG shares were split 40 to 1. Options granted prior to that date entitled the holder to acquire 40 Novartis AG shares per option. The figures in the tables below have been restated for grants before 2002 to reflect this change. The number of options granted depends on the performance of the individuals and the Business Unit in which they work.

	2004		2003		
	Options	Weighted average exercise price	Options	Weighted average exercise price	
	(millions)	(\$)	(millions)	(\$)	
Options outstanding at January 1	21.0	44.3	11.5	43.6	
Granted	4.9	46.1	9.8	36.4	
Exercised	(6.3)	37.6	(0.1)	36.0	
Cancelled	(1.0)	37.4	(0.2)	36.0	
Outstanding at December 31	18.6	48.1	21.0	44.3	
Exercisable at December 31	5.0	54.6	6.0	47.8	
Weighted average fair value of options granted during the year (\$)		11		15	

All options were granted at an exercise price which was equal to or greater than the market price of the Group's shares at the grant date.

#### 26. Employee share participation plans (Continued)

The following table summarizes information about share options outstanding at December 31, 2004:

	Options outstanding			Options exercisable		
Range of exercise prices	Number outstanding	Average remaining contractual life	Weighted average exercise price	Number exercisable	Weighted average exercise price	
(\$)	(millions)	(years)	(\$)	(millions)	(\$)	
35–39	0.2	2.1	37.4	0.2	37.4	
40–44	9.0	7.1	43.1	0.1	42.8	
45–49	0.6	4.2	45.2	0.5	45.2	
50–54	7.5	7.4	52.1	2.8	54.7	
55–59						
60-64	1.3	4.5	61.2	1.4	61.2	
Total	18.6	<u>6.9</u>	48.1	5.0	54.6	

#### b) Novartis US ADS Incentive Plan

The US ADS Incentive Plan was introduced in 2001 and supplements the previous US Management ADS Appreciation Cash Plan. Under the US ADS Incentive Plan, options are granted annually on Novartis ADSs at a pre-determined exercise price as part of the remuneration of US-based executives and other selected employees. As of 2004, options granted under this plan are tradable. The number of options granted depends on the performance of the individuals and of the Division/Business Unit in which they work. Options are exercisable after three years and terminate after ten years. Under the previous US Management ADS Appreciation Cash Plan, Novartis US-based employees in the USA were entitled to cash compensation equivalent to the increase in the value of Novartis ADSs compared to the market price of the ADSs at the grant date.

	2004			2003
	ADS Options	Weighted average exercise price	ADS Options	Weighted average exercise price
	(millions)	(\$)	(millions)	(\$)
Options outstanding at January 1	40.6	37.7	23.2	39.3
Granted	9.2	46.1	20.0	36.4
Exercised	(2.4)	40.8	(0.1)	41.8
Cancelled	(3.3)	38.5	(2.5)	38.0
Outstanding at December 31	44.1	39.1	40.6	37.7
Exercisable at December 31	6.3	42.5	1.2	38.8
Weighted average fair value of options granted during the year (\$)		16		17

All ADS options were granted at an exercise price which was equal to the market price of the ADS at the grant date.

#### 26. Employee share participation plans (Continued)

The following table summarizes information about ADS options outstanding at December 31, 2004:

	ADS options outstanding			ADS options outstanding ADS option			ons exercisable	
Range of exercise prices	Number outstanding	Average remaining contractual life	Weighted average exercise price	Number exercisable	Weighted average exercise price			
(\$)	(millions)	(years)	(\$)	(millions)	(\$)			
30–34	0.1	5.2	33.9	0.1	34.2			
35–39	30.6	6.7	36.8	1.0	38.2			
40–44	5.3	5.2	41.9	5.1	43.4			
45–49	8.1	8.1	46.1	0.1	45.4			
Total	44.1	6.8	39.1	6.3	42.5			

#### Share plans

#### a) Long-Term Performance Plan

This plan is offered to selected executives. Under the Long-Term Performance Plan, participants are awarded the right to earn Novartis AG shares. Actual payouts, if any, are determined with the help of a formula which measures, among other things, Novartis' performance using economic value added relative to predetermined strategic plan targets. Additional functional objectives may be considered in the evaluation of performance. If performance is below the threshold level of the pre-determined targets, no shares will be earned. During 2004 a total of 411,041 shares (2003: 507,507 shares) were granted to executives.

#### b) Leveraged Share Savings Plan

Participants under this plan can make an election to receive all or part of their annual incentive award in Novartis AG shares. Shares received under the plan are blocked for a five year period after the grant date. At the end of the blocking period, Novartis will match the respective shares on a one-for-one basis. During 2004, 254,390 shares (2003: 279,619 shares) were granted to participants.

#### c) Swiss Employee Share Ownership Plan

The Swiss Employee Share Ownership Plan (ESOP) provides for the annual variable incentive to be delivered wholly in the form of Novartis AG shares at a fixed date at a fair market value at that date. Employees are free to sell 50% or 100% of these shares immediately. Shares received under the plan have a three year blocking period and are matched with one share for every two shares held at the end of the blocking period. In 2004 the Swiss employees received 3,080,673 shares (2003: 3,942,687 shares) under this scheme.

#### d) Restricted Share Plan

Under the Restricted Share Plan, employees may be granted restricted share awards either as a result of a general grant or as a result of an award based on having met certain performance criteria. Shares granted under this Plan generally have a five-year vesting period. During 2004 a total of 485,609 shares (2003: 390,053 shares) were granted to executives and selected employees.

#### 26. Employee share participation plans (Continued)

Movements in Novartis AG shares held by the Novartis Foundation for Employee Participation were as follows:

	2004	2003
	Number of shares	Number of shares
	(000)	(000)
January 1	93,300	95,072
Shares bought, net	857	1,163
Shares distributed to employees	(6,839)	(2,935)
December 31	87,318	93,300

The market value of the Novartis AG shares held by the Foundation at December 31, 2004 was \$4.4 billion (2003: \$4.2 billion).

#### 27. Related parties

The Novartis Group has formed certain foundations with the purposes of advancing employee welfare, employee share participation, employee education, research and charitable contributions. The charitable foundations foster health care and social development in rural countries. Each of these foundations is autonomous and its board is responsible for its respective administration in accordance with the foundation's purpose and applicable law.

The Novartis Foundation for Employee Participation has not been included in the consolidated financial statements prepared under IFRS as Interpretation No. 12 of the Standing Interpretations Committee exempts post-employment and equity compensation plans from its scope. The total assets of this Foundation as of December 31, 2004 included 87.3 million shares of Novartis AG with a market value of \$4.4 billion. As of December 31, 2003, the assets included 93.3 million Novartis shares with a market value of \$4.2 billion. This Foundation is consolidated under US GAAP and is included as a reconciling item in the US GAAP reconciliation.

In 2004, the Group made short-term deposits totaling \$713 million with the above mentioned foundations and received short-term loans totaling \$16 million from them. In 2003, the Group made short-term deposits totaling \$651 million with the foundations and received short-term loans totaling \$8 million from them.

In addition, there are approximately fifteen other foundations that were established for charitable purposes that have not been consolidated as the Group does not receive a benefit therefrom. As of December 31, 2004 these foundations held approximately 6.1 million shares of Novartis, with a cost of approximately \$35 million.

See notes 5, 10, 25, 26 and 28 to the consolidated financial statements for disclosure of other related party transactions and balances.

#### 28. Commitments and contingencies

#### **Spin-off of Novartis Agribusiness**

All remaining significant matters in connection with the 1999 Master Agreement between Novartis AG and AstraZeneca Plc for the spin-off and merger of their respective agrochemical businesses into Syngenta AG have been completed during 2003.

#### **Chiron Corporation**

In connection with its original investment in January 1996 in Chiron:

- Novartis has agreed to purchase up to \$500 million of new Chiron equity at fair value, at Chiron's request. To date, Chiron has made no such request.
- Novartis has agreed to guarantee up to \$703 million of Chiron debt. Utilization of the guarantee in excess of \$403 million reduces the equity put amount mentioned above. Novartis' obligation under the guarantee is only effective if Chiron defaults on the debt.
- Chiron has granted to Novartis an option to purchase newly issued shares of equity securities directly from Chiron at fair market value. Novartis may exercise this option at any time subject to certain conditions, including a limitation on Novartis' aggregate ownership not to exceed 55% of Chiron's then outstanding common stock.

The outstanding equity put and guarantee expire no later than 2011.

#### Leasing commitments

Commitments arising from fixed-term operational leases in effect at December 31 are as follows:

	2004
	(\$ millions)
2005	233
2006	181
2007	123
2008	80
2009	63
Thereafter	246
Total	926
Expense of current year	287

#### 28. Commitments and contingencies (Continued)

#### **Research & Development commitments**

The Group has entered into long-term research agreements with various institutions including potential milestone payments. As of December 31, 2004 they are as follows:

	Unconditional commitments 2004	Potential milestone payments 2004	Total 2004
	(\$ millions)	(\$ millions)	(\$ millions)
2005	285	91	376
2006	169	70	239
2007	76	88	164
2008	75	67	142
2009	38	133	171
Thereafter	22	133	155
Total	665	582	1,247

#### Other commitments

The Novartis Group entered into various purchase commitments for services and materials as well as for equipment as part of the ordinary business. These commitmens are not in excess of current market prices in all material respects and reflect normal business operations.

#### Contingencies

Group companies have to observe the laws, government orders and regulations of the country in which they operate. A number of them are currently involved in administrative proceedings arising out of the normal conduct of their business. In the opinion of Group management, however, the outcome of these actions will not materially affect the Group's financial position, result of operations or cash flow.

The material components of the Group's potential environmental liability consist of a risk assessment based on investigation of the various sites identified by the Group as at risk for environmental exposure. The Group's future remediation expenses are affected by a number of uncertainties. These uncertainties include, but are not limited to, the method and extent of remediation, the percentage of material attributable to the Group at the remediation sites relative to that attributable to other parties, and the financial capabilities of the other potentially responsible parties.

The Group is also subject to certain legal and product liability claims. Whilst provisions have been made for probable losses that management deems to be reasonable or appropriate there are uncertainties connected with these estimates. Note 19 contains more extensive discussion of these matters.

The Group does not expect the resolution of such uncertainties to have a material effect on the consolidated financial statements.

## 29. Principal currency translation rates

	2004	2003	2002
	(\$)	(\$)	(\$)
Year end rates used for the consolidated balance sheets:			
1 CHF	0.881	0.800	0.712
1 EUR	1.362	1.247	1.038
1 GBP	1.923	1.774	1.601
100 JPY	0.964	0.935	0.834
Average rates of the year used for the consolidated income and cash flow statements:			
1 CHF	0.805	0.745	0.643
1 EUR	1.243	1.131	0.946
1 GBP	1.831	1.636	1.503
100 JPY	0.926	0.867	0.802

#### 30. Events subsequent to the December 31, 2004 balance sheet date

The 2004 consolidated financial statements of the Novartis Group were approved by the Novartis AG Board of Directors on January 19, 2005.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004

The following descriptions describe the various types of entities within the Group:

- **Holding/Finance:** This entity is a holding company and/or performs finance functions for the Group.
- Sales: This entity performs sales and marketing activities for the Group.
- ▼ **Production:** This entity performs manufacturing and/or production activities for the Group.
- **Research:** The entity performs research and development activities for the Group.

		e/paid-in pital <sup>(1)</sup>	Equity Interest %	Activ	ities	
Argentina Novartis Argentina S.A., Buenos Aires	ARS	230.6 m	100			
	ARS	250.0 m	100	•		
Australia		11.0	100	_		
Novartis Australia Pty Ltd., North Ryde, NSW	AUD	11.0 m	100	•		
Novartis Pharmaceuticals Australia Pty Ltd., North Ryde, NSW . Novartis Consumer Health Australasia Pty Ltd., Mulgrave,	AUD	3.8 m	100	•		
Victoria	AUD	7.6 m	100	•	▼	
Novartis Animal Health Australasia Pty Ltd., North Ryde, NSW .	AUD	3.0 m	100	•		
Austria						
Novartis Pharma GmbH, Vienna	EUR	1.1 m	100	•		
Novartis Institutes for BioMedical Research GmbH & Co KG,	EUD	10.0	100			
Vienna	EUR EUR	10.9 m 100,000	100 100	-		
Sandoz GmbH, Vienna	EUR	32.7 m	100		-	
Novartis Animal Health GmbH, Kundl	EUR	37,000	100	- X	•	
	LUK	57,000	100	•		
Bangladesh						
Novartis (Bangladesh) Limited, Dhaka	BDT	162.5 m	60	•	▼	
Belgium						
N.V. Novartis Management Services S.A., Vilvoorde	EUR	7.5 m	100			
N.V. Novartis Pharma S.A., Vilvoorde	EUR	7.1 m	100	•		
N.V. Novartis Consumer Health S.A., Brussels	EUR	4.3 m	100	•		
N.V. Nutrition & Santé Benelux S.A., Brussels	EUR	509,630	97	•		
N.V. CIBA Vision Benelux S.A., Mechelen	EUR	62,000	100	•		
Bermuda						
Triangle International Reinsurance Ltd., Hamilton	CHF	1.0 m	100			
Novartis Securities Investment Ltd., Hamilton	CHF	30,000	100			
Novartis International Pharmaceutical Ltd., Hamilton	CHF	10.0 m	100	• •		
Brazil						
Novartis Biociências S.A., São Paulo	BRL	186.7 m	100	•	▼	
Novartis Saúde Animal Ltda., São Paulo	BRL	19.9 m	100	•	▼	

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated;

- above 20% and up to 50% of the voting rights-investment in associated company-equity method accounting.

(1) Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

		e/paid-in bital <sup>(1)</sup>	Equity Interest %	Activities	
CanadaNovartis Pharmaceuticals Canada Inc., Dorval/MontrealSabex Inc., Boucherville, QuebecNovartis Consumer Health Canada Inc., Mississauga, OntarioCIBA Vision Canada Inc., Mississauga, Ontario	CAD CAD CAD CAD	$0^{(2)}$ 2 2 1	100 100 100 100	* * * *	<b>A</b>
Chile Novartis Chile S.A., Santiago de Chile	CLP	2.0 bn	100	•	
ChinaBeijing Novartis Pharma Ltd., BeijingNovartis Pharmaceuticals (HK) Limited, Hong KongShanghai Novartis Trading Ltd., Shanghai	CNY HKD CNY	111.3 m 200 20.3 m	78 100 100	• • •	
Colombia Novartis de Colombia S.A., Santafé de Bogotá	СОР	20.9 bn	100	<b>ب</b>	
Croatia Lek Zagreb d.o.o., Zagreb	HRK	25.6 m	100	٠	
Czech Republic Novartis s.r.o., Prague	CZK	51.5 m	100	•	
<b>Denmark</b> Novartis Healthcare A/S, Copenhagen	DKK	10.0 m	100	•	
Ecuador Novartis Ecuador S.A., Quito	USD	209,193	100	•	
Egypt Novartis Pharma S.A.E., Cairo Novartis Egypt (Healthcare) S.A.E., Cairo	EGP EGP	33.8 m 250,000	99 95	•	
Finland Novartis Finland Oy, Espoo	EUR	459,000	100	•	
FranceNovartis Groupe France S.A., Rueil-MalmaisonNovartis Pharma S.A.S., Rueil-MalmaisonSandoz S.A.S., Levallois-PerretNovartis Santé Familiale S.A.S., Rueil-MalmaisonNovartis Santé Animale S.A.S., Rueil-MalmaisonNovartis Nutrition S.A.S., RevelNutrition et Santé S.A.S., RevelCIBA Vision S.A.S., Blagnac	EUR EUR EUR EUR EUR EUR EUR	103.0 m 43.4 m 2.6 m 21.9 m 900,000 300,000 300,000 30.2 m 1.8 m	100 100 100 100 100		•

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated; — above 20% and up to 50% of the voting rights—investment in associated company—equity method accounting.

<sup>(1)</sup> Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

<sup>(2)</sup> Shares of no par value.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

Germany       EUR       35.8 m       100       •       ▲         Novartis Pharma GubH, Nuremberg       EUR       25.6 m       100       •       ▲         Sandoz Pharma Cubuktions GubH, Wehr       EUR       2.0 m       100       •       ▲         Sandoz Industrial Products GubH, Frankfurt am Main       EUR       2.6 m       100       •       ▲         Novartis Nutrition GubH, Grossotheim       EUR       2.5 m       100       •       ▲         Novartis Nutrition GubH, Grossotheim       EUR       2.5 m       100       •       ▲         CIBA Vision GubH, Grossotheim       EUR       2.5 m       100       •       ▲         Novartis Gurinstop Limited, Gibraltar       CHF       130.0 m       100       •       ▼       ▲         Novartis Grimsby Limited, Frimley/Camberly.       GBP       2.5 m       100       •       ▼       ▲         Novartis Grimsby Limited, Frimley/Camberly.       GBP       2.5 m       100       •       ▼       ▲         Novartis Grimsby Limited, Frimley/Camberly.       GBP       2.5 m       100       •       ▼       ▲         Novartis Grimsby Limited, Suthampton       GBP       25.000       100       ●       ▼ <td< th=""><th></th><th colspan="2">Share/paid-in capital<sup>(1)</sup></th><th>Equity Interest %</th><th></th><th>Activi</th><th>ities</th><th></th></td<>		Share/paid-in capital <sup>(1)</sup>		Equity Interest %		Activi	ities	
Novariis Deutschland GmbH, Wehr       EUR       25.6       100         Novariis Pharma GmbH, Nurenberg       EUR       25.6       100         Sandoz Pharma Groduktions GmbH, Kwhr       EUR       2.6       100         Sandoz Industrial Products GmbH, Frankfurt am Main       EUR       2.6       100         Novariis Onsumer Health GmbH, Munich       EUR       2.6       100       ▼         Novariis Orismer Health GmbH, Munich       EUR       2.6       100       ▼       ▲         Novariis Orismer Health GmbH, Munich       EUR       2.5       100       ▼       ▲         CIBA Vision GmbH, Grosswallstadt       EUR       15.4       100       ▼       ▲         Gibraltar       Gibraltar       GBP       25.5       100       ▼       ▲         Novariis Vittirited, Frimley/Camberly       GBP       2.5.7       100       ▼       ▲         Novariis Cuimited, Frimley/Camberly       GBP       2.5.0       100       ▼       ▲         Novariis Cuimited, Frimley/Camberly       GBP       2.0.m       100       ▼       ▲         Novariis Grimsby Limited, Frimley/Camberly       GBP       2.0.0m       100       ●       ▲         Novariis Grimsby Limited, Southampton	Germany							
Novaris Pharma GmbH, Nuremberg       EUR       25.6 m       100 <ul> <li>Novaris Pharma Produktions GmbH, Wehr</li> <li>EUR</li> <li>2.0 m</li> <li>100</li> <li>Sandoz Pharmaceuticals GmbH, Ismanfung</li> <li>EUR</li> <li>5.1 m</li> <li>100</li> <li>Zadaz Industrial Products GmbH, Ismanfung</li> <li>EUR</li> <li>EUR</li> <li>5.1 m</li> <li>100</li> <li>Xadoz Industrial Products GmbH, Frankfurt am Main</li> <li>EUR</li> <li>EUR</li> <li>2.6 m</li> <li>100</li> <li>Xadoz Industrial Products GmbH, Hanich</li> <li>EUR</li> <li>EUR</li> <li>2.6 m</li> <li>100</li> <li>Xadoz Industrial Products GmbH, Hanich</li> <li>EUR</li> <li>EUR</li> <li>2.6 m</li> <li>100</li> <li>Xadoz Industrial Products GmbH, Grossontheim</li> <li>EUR</li> <li>EUR</li> <li>15.4 m</li> <li>100</li> <li>Xadoz Industrial Pharmaceuticals UK Limited, Frimley/Camberly</li> <li>GBP</li> <li>2.5 m</li> <li>100</li> <li>Sandoz Limited, Frimley/Camberly</li> <li>GBP</li> <li>2.0 m</li> <li>100</li> <li>Xadoz Limited, Frimley/Camberly</li> <li>GBP</li> <li>2.0 m</li> <li>100</li> <li>Xadoz Limited, Southampton</li> <li>GBP</li> <li>2.000</li> <li>Xadoz Private Limited, Kumbeta</li> <li>Inria</li> <li>Inria</li> <li>Novartis Grosson (UK) Limited, Southampton</li> <li>GBP</li> <li>100</li> <li>Xadoz Private Limited, Mumbai<td>5</td><td>FUR</td><td>35.8 m</td><td>100</td><td></td><td></td><td></td><td></td></li></ul>	5	FUR	35.8 m	100				
Novaris Pharma Produktions GmbH, Ismaning       EUR       2.0 m       100         Sandoz Pharmaceuticals GmbH, Ismaning       EUR       5.1 m       100         Novaris Consumer Health GmbH, Munich       EUR       2.6 m       100         Novaris Nutrition GmbH, Munich       EUR       2.6 m       100         CIBA Vision Vertriebs GmbH, Grossostheim       EUR       2.6 m       100         CIBA Vision GmbH, Grossostheim       EUR       2.5 m       100         Gibraltar       CHF       130.0 m       100       ✓         Novaris Nutrition GmbH, Grossostheim       EUR       15.4 m       100       ✓         Gibraltar       CHF       130.0 m       100       ✓       ▲         Novaris Lumited, Finley/Camberly       GBP       2.5 m       100       ✓       ▲         Novaris Consumer Health UK Limited, Horsham       GBP       2.0 m       100       ✓       ▲         Novaris Consumer Health UK Limited, Horsham       GBP       5000       100       ✓       ▲         Novaris Minal Health UK Limited, Horsham       GBP       50,000       100       ✓       ▲         Novaris Indina Health UK Limited, Southampton       GBP       50,000       100       ✓       ▲	,				-			
Sandoz Pharmaceuticals GmbH, Ismaning       EUR       5.1 m       100         Sandoz Industrial Products GmbH, Frankfurt am Main       EUR       2.6 m       100         Novartis Consumer Health GmbH, Munich       EUR       14.6 m       100         Novartis Nutrition GmbH, Grossostheim       EUR       2.6 m       100         CIBA Vision GmbH, Grossostheim       EUR       2.6 m       100         CIBA Vision GmbH, Grossostheim       EUR       2.6 m       100         Gibrattar       Novistia Insurance Limited, Gibraltar       CHF       130.0 m       100         Novartis UK Limited, Frimley/Camberly       GBP       25.5 m       100       •         Novartis Bramaceuticals UK Limited, Frimley/Camberly       GBP       2.0 m       100       •         Novartis Consumer Health UK Limited, Horsham       GBP       2.0 m       100       •       •         Novartis Animal Health UK Limited, Royston       GBP       100,000       100       •       •       •         Novartis Khengary Healthcare Limited Liability Company,       GBP       50,000       100       •       •         Novartis India Limited, Mumbai       INR       159.8 m       51       •       •       •         Novartis Hungary Healthcare Limited L						•	_	
Sandoz Industrial Products GmbH, Frankfurt am Main       EUR       2.6 m       100       ▼       ▲         Novarits Consumer Health GmbH, Munich       EUR       14.6 m       100       ▼       ▲         Novarits Consumer Health GmbH, Munich       EUR       2.5 m       100       ▼       ▲         CIBA Vision CmbH, Grosswallstadt       EUR       15.4 m       100       ▼       ▲         Gibraltar       Novista Insurance Limited, Gibraltar       CHF       130.0 m       100       ■         Novarits KL Limited, Frimley/Camberly       GBP       25.5 m       100       ■         Novarits KL Limited, Frimley/Camberly       GBP       2.5 m       100       ■         Novarits KL Limited, Frimley/Camberly       GBP       2.0 m       100       ▼       ▲         Novarits Grimsby Limited, Frimley/Camberly       GBP       2.0 m       100       ▼       ▲         Novarits Consumer Health UK Limited, Horsham       GBP       2.0 m       100       ▼       ▲         Novarits (Hellas) S.A.C.I., Athens       EUR       14.6 m       100       ●       ▲         Indagest       HUF       545.6 m       100       ●       ●       ▼         Indapest       Inwited, Mumbai								
Novartis Consumer Health GmbH, Munich       EUR       14.6 m       100       Image: Construction Constructin Constructin Construction Construction Construction Construction						•		
Novartis Nutrition GmbH, Munich       EUR       23.5 m       100       ◆       ▼       ▲         CIBA Vision GmbH, Grosswallstadt       EUR       2.6 m       100       ◆       ▼       ▲         Gibraltar       Novista Insurance Limited, Gibraltar       CHF       130.0 m       100       ●       ▼       ▲         Gibraltar       Novartis UK Limited, Frimley/Camberly       GBP       25.5 m       100       ●       ▼       ▲         Novartis VK Limited, Frimley/Camberly       GBP       23.2 m       100       ▼       ▲         Novartis Grinsby Limited, Frimley/Camberly       GBP       20 m       100       ▼       ▲         Novartis Grinsby Limited, Royston       GBP       2.0 m       100       ◆       ▼       ▲         Novartis Animal Health UK Limited, Royston       GBP       25,000       100       ◆       ▼       ▲         Novartis Idelas) S.A.C.I., Athens       EUR       14.6 m       100       ◆       ▼       ▲         Indiae       Novartis India Limited, Mumbai       INR       159.8 m       51       Sandoz Private Limited Jubility Company, Budapest       100       ▼       ▼         Indonesia       IDR       IDR       7.7 bn       69	Sandoz Industrial Products GmbH, Frankfurt am Main	EUR	2.6 m	100		•	•	
CIBA Vision Vertrichs GmbH, Grossostheim       EUR       2.6 m       100         CIBA Vision GmbH, Grosswallstadt       EUR       15.4 m       100         Gibraltar       Novista Insurance Limited, Gibraltar       CHF       130.0 m       100         Novista Insurance Limited, Gibraltar       CHF       130.0 m       100       ■         Great Britain       Novartis brarmaceutical KL Limited, Frimley/Camberly       GBP       25.5 m       100       ■         Novartis Grimsby Limited, Frimley/Camberly       GBP       230.2 m       100       ■       ▼       ▲         Sandoz Limited, Bordon       GBP       20 m       100       ●       ▼       ▲         Novartis Grosswer Health UK Limited, Horshan       GBP       2.0 m       100       ●       ▼       ▲         Novartis Hellas) S.A.C.I., Athens       EUR       14.6 m       100       ●       ▼       ▲         Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100       ●       ▼       ▲         Indonesia       INR       159.8 m       51       ●       ▼       ▼       ■         PT Novartis India Limited, Numbai       IDR       11.9 bn       100       ▼       ▼       ■ <td>Novartis Consumer Health GmbH, Munich</td> <td>EUR</td> <td>14.6 m</td> <td>100</td> <td></td> <td>•</td> <td>▼</td> <td></td>	Novartis Consumer Health GmbH, Munich	EUR	14.6 m	100		•	▼	
CIBA Vision GmbH, Grosswallstadt       EUR       15.4 m       100       ◆       ▲         Gibraltar       Nvista Insurance Limited, Gibraltar       CHF       130.0 m       100       ■         Great Britain       Novartis UK Limited, Frimley/Camberly       GBP       25.5 m       100       ■         Novartis VK Limited, Frimley/Camberly       GBP       230.2 m       100       ●       ▼       ▲         Sandoz Limited, Bordon       GBP       200.2 m       100       ●       ▼       ▲         Novartis Chimsby Limited, Frimley/Camberly       GBP       230.2 m       100       ●       ▼       ▲         Novartis Chimsby Limited, Frimley/Camberly       GBP       200.0 m       100       ●       ▼       ▲         Novartis Aninal Health UK Limited, Horsham       GBP       25.000       100       ●       ▼       ▲         IBA Vision (UK) Limited, Southampton       GBP       550,000       100       ●       ▼       ▲         Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100       ●       ▼       ■         Indanesia       INR       159.8 m       51       S1       ▼       ▼       ■       ■       ■       ■<	Novartis Nutrition GmbH, Munich	EUR	23.5 m	100		•	$\mathbf{V}$	
CIBA Vision GmbH, Grosswallstadt       EUR       15.4 m       100       ◆       ▲         Gibraltar       Nvista Insurance Limited, Gibraltar       CHF       130.0 m       100       ■         Great Britain       Novartis UK Limited, Frimley/Camberly       GBP       25.5 m       100       ■         Novartis VK Limited, Frimley/Camberly       GBP       230.2 m       100       ●       ▼       ▲         Sandoz Limited, Bordon       GBP       200.2 m       100       ●       ▼       ▲         Novartis Chimsby Limited, Frimley/Camberly       GBP       230.2 m       100       ●       ▼       ▲         Novartis Chimsby Limited, Frimley/Camberly       GBP       200.0 m       100       ●       ▼       ▲         Novartis Aninal Health UK Limited, Horsham       GBP       25.000       100       ●       ▼       ▲         IBA Vision (UK) Limited, Southampton       GBP       550,000       100       ●       ▼       ▲         Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100       ●       ▼       ■         Indanesia       INR       159.8 m       51       S1       ▼       ▼       ■       ■       ■       ■<	CIBA Vision Vertriebs GmbH. Grossostheim	EUR	2.6 m	100		•		
Gibraltar       Novista Insurance Limited, Gibraltar       CHF       130.0 m       100         Great Britain       Novartis Uk Limited, Frimley/Camberly       GBP       25.5 m       100       •         Novartis Pharmaceuticals UK Limited, Frimley/Camberly       GBP       230.2 m       100       •       •         Novartis Grimsby Limited, Frimley/Camberly       GBP       230.2 m       100       •       •       •         Novartis Consumer Health UK Limited, Horsham       GBP       25.000       100       •       •       •       •         Novartis Consumer Health UK Limited, Royston       GBP       100,000       100       •			15.4 m			- <b>*</b> -	•	
Novista Insurance Limited, Gibraltar.       CHF       130.0 m       100         Great Britain       GBP       25.5 m       100         Novartis UK Limited, Frimley/Camberly.       GBP       5.4 m       100         Novartis Grimsby Limited, Frimley/Camberly.       GBP       230.2 m       100         Sandoz Limited, Bordon       GBP       230.0 m       100         Novartis Grimsby Limited, Frimley/Camberly       GBP       230.0 m       100         Novartis Grossumer Health UK Limited, Horsham       GBP       25,000       100         Novartis Animal Health UK Limited, Royston       GBP       100,000       100         Novartis Grimsby Limited, Southampton       GBP       550,000       100       Image: Comparison of the co		Lon	1011 111	100		•		-
Great Britain         Novartis UK Limited, Frimley/Camberly.       GBP       25.5 m       100         Novartis Grimsby Limited, Frimley/Camberly.       GBP       230.2 m       100         Novartis Grimsby Limited, Frimley/Camberly.       GBP       230.2 m       100         Sandoz Limited, Bordon       GBP       2.0 m       100         Novartis Consumer Health UK Limited, Horsham       GBP       20,000       100         Novartis Consumer Health UK Limited, Royston       GBP       120,000       100         Novartis Grimsby Limited, Southampton       GBP       550,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis India Limited, Mumbai       INR       14.6 m       100         Hungary       Novartis India Limited, Mumbai       INR       159.8 m       51       ▼         Novartis India Limited, Mumbai       INR       159.8 m       51       ▼         Sandoz Private Limited, Mumbai       INR       100       ▼       ▼         Indonesia       IDR       7.7 bn       69       ▼       ▼         PT Novartis Biochemie, Jakarta       IDR       1DR       100       ▼       ▼         Novartis R	Gibraltar							
Novartis UK Limited, Frimley/CamberlyGBP $25.5 \text{ m}$ $100$ Novartis Pharmaceuticals UK Limited, Frimley/CamberlyGBP $32.0 \text{ m}$ $100$ Sandoz Limited, BordonGBP $2.0 \text{ m}$ $100$ Novartis Consumer Health UK Limited, HorshamGBP $2.0 \text{ m}$ $100$ Novartis Consumer Health UK Limited, HorshamGBP $2.0 \text{ m}$ $100$ Novartis Animal Health UK Limited, RoystonGBP $20.0 \text{ m}$ $100$ Order UBA Vision (UK) Limited, SouthamptonGBP $550,000$ $100$ <b>Greece</b> GBP $100,0000$ $100$ Novartis Hungary Healthcare Limited Liability Company, BudapestHUF $545.6 \text{ m}$ $100$ Novartis India Limited, MumbaiINR $159.8 \text{ m}$ $51$ Novartis Biochemie, JakartaIDR $7.7 \text{ bn}$ $69$ PT Novartis Biochemie, JakartaIDR $11.9 \text{ bn}$ $100$ <b>Ireland</b> Novartis Freland Limited, Ringaskiddy, County CorkEUR $2.0 \text{ m}$ Novartis Farma S.p.A., OriggioEUR $18.2 \text{ m}$ $100$ Novartis Farma S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ Novartis Co	Novista Insurance Limited, Gibraltar	CHF	130.0 m	100				
Novartis UK Limited, Frimley/CamberlyGBP $25.5 \text{ m}$ $100$ Novartis Pharmaceuticals UK Limited, Frimley/CamberlyGBP $32.0 \text{ m}$ $100$ Sandoz Limited, BordonGBP $2.0 \text{ m}$ $100$ Novartis Consumer Health UK Limited, HorshamGBP $2.0 \text{ m}$ $100$ Novartis Consumer Health UK Limited, HorshamGBP $2.0 \text{ m}$ $100$ Novartis Animal Health UK Limited, RoystonGBP $20.0 \text{ m}$ $100$ Order UBA Vision (UK) Limited, SouthamptonGBP $550,000$ $100$ <b>Greece</b> GBP $100,0000$ $100$ Novartis Hungary Healthcare Limited Liability Company, BudapestHUF $545.6 \text{ m}$ $100$ Novartis India Limited, MumbaiINR $159.8 \text{ m}$ $51$ Novartis Biochemie, JakartaIDR $7.7 \text{ bn}$ $69$ PT Novartis Biochemie, JakartaIDR $11.9 \text{ bn}$ $100$ <b>Ireland</b> Novartis Freland Limited, Ringaskiddy, County CorkEUR $2.0 \text{ m}$ Novartis Farma S.p.A., OriggioEUR $18.2 \text{ m}$ $100$ Novartis Farma S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ $100$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ Novartis Consumer Health S.p.A., OriggioEUR $2.6 \text{ m}$ Novartis Co								
Novartis Pharmaceuticals UK Limited, Frimley/Camberley								
Novartis Grimsby Limited, Frimley/Camberly       GBP       230.2 m       100         Sandoz Limited, Bordon       GBP       2.0 m       100         Novartis Consumer Health UK Limited, Horsham       GBP       25,000       100         Novartis Consumer Health UK Limited, Royston       GBP       100,000       100         Novartis Animal Health UK Limited, Royston       GBP       100,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100         India       Novartis India Limited, Mumbai       INR       159.8 m       51         Novartis Bindia Limited, Mumbai       INR       159.8 m       51         Sandoz Private Limited, Mumbai       INR       159.8 m       100         Indonesia       IDR       7.7 bn       69       ▼         PT Novartis Bichemie, Jakarta       IDR       100       ▼       ▼         Indonesia       IDR       11.9 bn       100       ▼         Ireland       Novartis Ringaskiddy, County Cork       EUR       2.0 m       100	Novartis UK Limited, Frimley/Camberly	GBP	25.5 m	100				
Sandoz Limited, Bordon       GBP       2.0 m       100         Novartis Consumer Health UK Limited, Horsham       GBP       25,000       100         Novartis Consumer Health UK Limited, Royston       GBP       100,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Hungary       Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100         India       Novartis India Limited, Mumbai       INR       159.8 m       51       ▼         Novartis India Limited, Mumbai       INR       32.0 m       100       ▼         Indonesia       PT       Novartis Biochemie, Jakarta       IDR       7.7 bn       69       ▼         PT Novartis Biochemie, Jakarta       IDR       11.9 bn       100       ▼         Ireland       Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ▼       ▲         Novartis Farma S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲ <t< td=""><td></td><td>GBP</td><td>5.4 m</td><td>100</td><td></td><td>•</td><td>V</td><td></td></t<>		GBP	5.4 m	100		•	V	
Sandoz Limited, Bordon       GBP       2.0 m       100         Novartis Consumer Health UK Limited, Horsham       GBP       25,000       100         Novartis Consumer Health UK Limited, Royston       GBP       100,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Hungary       Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100         India       Novartis India Limited, Mumbai       INR       159.8 m       51       ▼         Novartis India Limited, Mumbai       INR       32.0 m       100       ▼         Indonesia       PT       Novartis Biochemie, Jakarta       IDR       7.7 bn       69       ▼         PT Novartis Biochemie, Jakarta       IDR       11.9 bn       100       ▼         Ireland       Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ▼       ▲         Novartis Farma S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲ <t< td=""><td>Novartis Grimsby Limited, Frimley/Camberly</td><td>GBP</td><td>230.2 m</td><td>100</td><td></td><td></td><td>▼</td><td></td></t<>	Novartis Grimsby Limited, Frimley/Camberly	GBP	230.2 m	100			▼	
Novartis Consumer Health UK Limited, Horsham       GBP       25,000       100         Novartis Animal Health UK Limited, Royston       GBP       100,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Hungary       Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100         India       Novartis India Limited, Mumbai       INR       159.8 m       51         Novartis Biochemie, Jakarta       IDR       7.7 bn       69       ▼         PT Novartis Biochemie, Jakarta       IDR       11.9 bn       100       ▼         Ireland       Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Novartis Rangaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Gonsumer Health S.p.A., Origgio       EUR       2.6 m       100       ◆       ▼         Novartis Rongaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ◆       ▼		GBP	2.0 m	100		•		
Novartis Animal Health UK Limited, Royston       GBP       100,000       100         CIBA Vision (UK) Limited, Southampton       GBP       550,000       100         Greece       Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Hungary       Novartis Hungary Healthcare Limited Liability Company, Budapest       EUR       14.6 m       100         India       Novartis India Limited, Mumbai       HUF       545.6 m       100         Novartis India Limited, Mumbai       INR       159.8 m       51         Sandoz Private Limited, Mumbai       INR       32.0 m       100         Indonesia       PT       Novartis Biochemie, Jakarta       IDR       7.7 bn       69         PT CIBA Vision Batam, Batam       IDR       11.9 bn       100       ▼         Ireland       Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ▼       ▲         Novartis Farma S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Novartis Farma S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Novartis Formutia Products S.p.A., Origgio		GBP	25,000	100		. <b>.</b>	•	
CIBA Vision (UK) Limited, Southampton			,				·	
Greece Novartis (Hellas) S.A.C.I., Athens       EUR       14.6 m       100         Hungary Novartis Hungary Healthcare Limited Liability Company, Budapest       HUF       545.6 m       100         India Novartis India Limited, Mumbai       INR       159.8 m       51         Sandoz Private Limited, Mumbai       INR       32.0 m       100         PT Novartis Biochemie, Jakarta       IDR       7.7 bn       69         PT CIBA Vision Batam, Batam       IDR       11.9 bn       100         Ireland Novartis Ireland Limited, Ringaskiddy, County Cork       EUR       25,000       100         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       18.2 m       100         Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ✓         Sandoz S.p.A., Origgio       EUR       26.0 m       100       ✓         Novartis Farma S.p.A., Origgio       EUR       26.0 m       100       ✓       ✓         Novartis Consumer Health S.p.A., Origgio       EUR       26.0 m       100       ✓       ✓         Novartis Romageki Italia S.p.A., Origgio       EUR       2.0 m       100       ✓       ✓         Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ✓       ✓			,					
Novartis (Hellas) S.A.C.I., AthensEUR $14.6 \text{ m}$ $100  \blacklozenge$ Hungary Novartis Hungary Healthcare Limited Liability Company, BudapestHUF $545.6 \text{ m}$ $100  \bigstar$ IndiaINR $159.8 \text{ m}$ $51  \bigstar$ $\bigstar$ Novartis India Limited, MumbaiINR $159.8 \text{ m}$ $51  \bigstar$ $\bigstar$ Novartis India Limited, MumbaiINR $32.0 \text{ m}$ $100  \bigstar$ $\bigstar$ IndonesiaIDR $7.7 \text{ bn}$ $69  \bigstar$ $\bigstar$ PT Novartis Biochemie, JakartaIDR $7.7 \text{ bn}$ $69  \bigstar$ $\bigstar$ IrelandIDR $11.9 \text{ bn}$ $100  \bigstar$ $\bigstar$ Novartis Ireland Limited, DublinEUR $25,000  100  \bigstar$ $\bigstar$ Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR $20.0 \text{ m}$ $100  \bigstar$ $\bigstar$ Novartis Farma S.p.A., OriggioEUR $18.2 \text{ m}$ $100  \bigstar$ $\bigstar$ $\bigstar$ Sandoz S.p.A., OriggioEUR $2.6 \text{ m}$ $100  \bigstar$ $\bigstar$ $\bigstar$ Novartis Consumer Health S.p.A., OriggioEUR $2.9 \text{ m}$ $100  \bigstar$ $\bigstar$ Novartis Consumer Health S.p.A., OriggioEUR $2.9 \text{ m}$ $100  \bigstar$ Nutrition & Santé Italia S.p.A., OriggioEUR $1.7 \text{ m}$ $97  \bigstar$	CIDA VISION (UK) Limited, Southampton	GDP	330,000	100		•		
Novartis Hungary Healthcare Limited Liability Company, Budapest		EUR	14.6 m	100		٠		
Novartis Hungary Healthcare Limited Liability Company, Budapest	и							
BudapestHUF545.6 m100IndiaININR159.8 m51Novartis India Limited, MumbaiINR159.8 m51Sandoz Private Limited, MumbaiINR32.0 m100IndonesiaINR32.0 m100PT Novartis Biochemie, JakartaIDR7.7 bn69PT CIBA Vision Batam, BatamIDR11.9 bn100IrelandIDR11.9 bn100 $\checkmark$ Novartis Ireland Limited, DublinEUR25,000100Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100ItalyEUR18.2 m100 $\checkmark$ Sandoz S.p.A., OriggioEUR18.2 m100 $\checkmark$ Sandoz S.p.A., OriggioEUR2.6 m100 $\checkmark$ Novartis Consumer Health S.p.A., OriggioEUR2.9 m100 $\checkmark$ Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97 $\blacklozenge$	0.							
IndiaNovartis India Limited, MumbaiINRSandoz Private Limited, MumbaiINRSandoz Private Limited, MumbaiINR32.0 m100IndonesiaPT Novartis Biochemie, JakartaIDRPT CIBA Vision Batam, BatamIDR1DR11.9 bn100IrelandNovartis Ireland Limited, DublinEUR25,000100Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100ItalyNovartis Farma S.p.A., OriggioSandoz S.p.A., OriggioEUR100Sandoz Industrial Products S.p.A., RoveretoEUR2.6 m100Novartis Consumer Health S.p.A., OriggioEUR2.9 m100Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97			5 4 5 K	100		•		
Novartis India Limited, Mumbai       INR       159.8 m       51       ◆       ▼         Sandoz Private Limited, Mumbai       INR       32.0 m       100       ◆       ▼         Indonesia       PT Novartis Biochemie, Jakarta       IDR       7.7 bn       69       ◆       ▼         PT CIBA Vision Batam, Batam       IDR       11.9 bn       100       ▼       ▼         Ireland       IDR       11.9 bn       100       ▼       ▼         Novartis Ireland Limited, Dublin       EUR       25,000       100       ▼         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ●       ▼       ▲         Sandoz S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▼       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▼       ▲	Budapest	HUF	545.6 m	100		•		
Novartis India Limited, Mumbai       INR       159.8 m       51       ◆       ▼         Sandoz Private Limited, Mumbai       INR       32.0 m       100       ◆       ▼         Indonesia       PT Novartis Biochemie, Jakarta       IDR       7.7 bn       69       ◆       ▼         PT CIBA Vision Batam, Batam       IDR       11.9 bn       100       ▼       ▼         Ireland       IDR       11.9 bn       100       ▼       ▼         Novartis Ireland Limited, Dublin       EUR       25,000       100       ▼         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ●       ▼       ▲         Sandoz S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▼       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▼       ▲	India							
Sandoz Private Limited, MumbaiINR $32.0 \text{ m}$ 100 $\checkmark$ IndonesiaPT Novartis Biochemie, JakartaIDR7.7 bn69 $\checkmark$ PT CIBA Vision Batam, BatamIDR11.9 bn100 $\checkmark$ IrelandIDR11.9 bn100 $\checkmark$ Novartis Ireland Limited, DublinEUR25,000100 $\checkmark$ Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100 $\checkmark$ ItalyNovartis Farma S.p.A., OriggioEUR18.2 m100 $\checkmark$ $\checkmark$ Sandoz S.p.A., OriggioEUR2.6 m100 $\checkmark$ $\checkmark$ Novartis Consumer Health S.p.A., OriggioEUR2.6 m100 $\checkmark$ Nutrition & Santé Italia S.p.A., OriggioEUR2.9 m100 $\checkmark$		IND	150.0	51			-	
IndonesiaPT Novartis Biochemie, JakartaIDR7.7 bn69PT CIBA Vision Batam, BatamIDR11.9 bn100IrelandNovartis Ireland Limited, DublinEUR25,000100Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100ItalyNovartis Farma S.p.A., OriggioEUR18.2 m100 $\checkmark$ Sandoz S.p.A., OriggioEUR2.6 m100 $\checkmark$ Novartis Consumer Health S.p.A., OriggioEUR2.9 m100 $\checkmark$ Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97 $\bigstar$	,						<u> </u>	
PT Novartis Biochemie, JakartaIDR7.7 bn69 $\checkmark$ PT CIBA Vision Batam, BatamIDRIDR11.9 bn100 $\checkmark$ IrelandIDRIDR11.9 bn100 $\checkmark$ Novartis Ireland Limited, DublinEUR25,000100 $\diamond$ Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100 $\checkmark$ ItalyItalyEUR18.2 m100 $\checkmark$ Sandoz S.p.A., OriggioEUR18.2 m100 $\blacklozenge$ $\bigstar$ Sandoz Industrial Products S.p.A., RoveretoEUR2.6 m100 $\checkmark$ Novartis Consumer Health S.p.A., OriggioEUR2.9 m100 $\bigstar$ Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97 $\bigstar$	Sandoz Private Limited, Mumbai	INR	32.0 m	100		•	•	
PT Novartis Biochemie, JakartaIDR7.7 bn69 $\checkmark$ PT CIBA Vision Batam, BatamIDRIDR11.9 bn100 $\checkmark$ IrelandIDRIDR11.9 bn100 $\checkmark$ Novartis Ireland Limited, DublinEUR25,000100 $\diamond$ Novartis Ringaskiddy Limited, Ringaskiddy, County CorkEUR2.0 m100 $\checkmark$ ItalyItalyEUR18.2 m100 $\checkmark$ Sandoz S.p.A., OriggioEUR18.2 m100 $\blacklozenge$ $\bigstar$ Sandoz Industrial Products S.p.A., RoveretoEUR2.6 m100 $\checkmark$ Novartis Consumer Health S.p.A., OriggioEUR2.9 m100 $\bigstar$ Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97 $\bigstar$	Indonesia							
PT CIBA Vision Batam, Batam.       IDR       11.9 bn       100       ▼         Ireland       Novartis Ireland Limited, Dublin       EUR       25,000       100       ◆         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ▼       ▲         Sandoz S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Sandoz S.p.A., Origgio       EUR       2.6 m       100       ▼       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▼         Nutrition & Santé Italia S.p.A., Origgio       EUR       1.7 m       97       ◆		IDD	776.	(0			-	
Ireland         Novartis Ireland Limited, Dublin         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork         EUR       2.0 m         100         Vovartis Ringaskiddy Limited, Ringaskiddy, County Cork         EUR       2.0 m         100         Variation         EUR       100         Variation         EUR       18.2 m         100       ✓         Sandoz S.p.A., Origgio       EUR         Sandoz Industrial Products S.p.A., Rovereto       EUR         2.6 m       100         Novartis Consumer Health S.p.A., Origgio       EUR         Nutrition & Santé Italia S.p.A., Origgio       EUR         EUR       1.7 m         97						•	<u> </u>	
Novartis Ireland Limited, Dublin       EUR       25,000       100       ◆         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ●       ◆       ▲         Sandoz S.p.A., Origgio       EUR       18.2 m       100       ●       ◆       ▲         Sandoz Industrial Products S.p.A., Rovereto       EUR       2.6 m       100       ●       ◆         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ●         Nutrition & Santé Italia S.p.A., Origgio       EUR       1.7 m       97       ●	PT CIBA Vision Batam, Batam	IDR	11.9 bn	100			•	
Novartis Ireland Limited, Dublin       EUR       25,000       100       ◆         Novartis Ringaskiddy Limited, Ringaskiddy, County Cork       EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ●       ◆       ▲         Sandoz S.p.A., Origgio       EUR       18.2 m       100       ●       ◆       ▲         Sandoz Industrial Products S.p.A., Rovereto       EUR       2.6 m       100       ●       ◆         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ●         Nutrition & Santé Italia S.p.A., Origgio       EUR       1.7 m       97       ●	Iroland							
Novartis Ringaskiddy Limited, Ringaskiddy, County Cork EUR       2.0 m       100       ▼         Italy       Novartis Farma S.p.A., Origgio		EUD	25 000	100				
Italy       Novartis Farma S.p.A., Origgio       EUR       18.2 m       100       ▲         Sandoz S.p.A., Origgio       EUR       390,000       100       ▲         Sandoz Industrial Products S.p.A., Rovereto       EUR       2.6 m       100       ▲         Novartis Consumer Health S.p.A., Origgio       EUR       2.9 m       100       ▲         Nutrition & Santé Italia S.p.A., Origgio       EUR       1.7 m       97       ▲			· · · · ·			•	_	
Novartis Farma S.p.A., OriggioEUR18.2 m100Image: Constraint of the state of the sta	Novartis Ringaskiddy Limited, Ringaskiddy, County Cork	EUR	2.0 m	100			•	
Novartis Farma S.p.A., OriggioEUR18.2 m100Image: Constraint of the state of the sta	Italy							
Sandoz S.p.A., OriggioEUR390,000100Sandoz Industrial Products S.p.A., RoveretoEUR2.6 m100Novartis Consumer Health S.p.A., OriggioEUR2.9 m100Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97		EUD	10.2	100	-		-	
Sandoz Industrial Products S.p.A., RoveretoEUR2.6 m100Novartis Consumer Health S.p.A., OriggioEUR2.9 m100Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97	1 / 88				-		•	
Novartis Consumer Health S.p.A., OriggioEUREUR2.9 m100Nutrition & Santé Italia S.p.A., OriggioEUR1.7 m97			/			•	_	
Nutrition & Santé Italia S.p.A., Origgio EUR 1.7 m 97 🔶							•	
		EUR	2.9 m	100		•		
	Nutrition & Santé Italia S.p.A., Origgio	EUR	1.7 m	97		•		
	1 000	EUR	2.4 m	100				
						•		

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated; — above 20% and up to 50% of the voting rights—investment in associated company—equity method accounting.

(1) Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

	Share/paid-in capital <sup>(1)</sup>		Equity Interest %		Activ	ities	
Japan							
Novartis Pharma K.K., Tokyo	JPY	6.0 bn	100		•		
Ciba-Geigy Japan Limited, Tokyo	JPY	8.5 bn	100			▼	
CIBA Vision K.K., Tokyo	JPY	495.0 m	100		•		
Liechtenstein							
Novista Insurance Aktiengesellschaft, Vaduz	CHF	5.0 m	100				
Novisia insurance Aktiongesenschaft, vaduz	CIII	5.0 m	100	-			
Luxembourg							
Novartis Investments S.à r.l., Luxembourg	USD	2.6 bn	100				
Malavsia							
Novartis Corporation (Malaysia) Sdn. Bhd., Kuala Lumpur	MYR	3.3 m	70				
Novarus Corporation (Malaysia) Sun. Did., Ruaia Eulipur	MITIC	5.5 m	70		•		
Mexico							
Novartis Farmacéutica, S.A. de C.V., Mexico City	MXN	287.7 m	100		•	▼	
Productos Gerber, S.A. de C.V., Querétaro	MXN	12.5 m	100		•	▼	
Netherlands							
Novartis Netherlands B.V., Arnhem	EUR	1.4 m	100				
Novartis Pharma B.V., Arnhem	EUR	4.5 m	100	-			
Sandoz B.V., Weesp	EUR	907,570	100			-	
Novartis Consumer Health B.V., Breda	EUR	23,830				<b>.</b>	
Novarus Consumer rieatui D.v., Dieda	EUK	25,850	100		•	•	
Netherlands Antilles							
Sandoz N.V., Curação	USD	6,000	100		•		
New Zealand							
	NZD	820.000	100				
Novartis New Zealand Ltd., Auckland	NZD	820,000	100		•		
Norway							
Novartis Norge AS, Oslo	NOK	1.5 m	100		•		
D-12-4							
Pakistan	DVD	24.8 m	98			-	
Novartis Pharma (Pakistan) Limited, Karachi	PKR	24.8 m	98		•	•	
Panama							
Novartis Pharma (Logistics), Inc., Panama	USD	10,000	100		•		
Philippines	מדום	200.0	100				
Novartis Healthcare Philippines, Inc., Makati/Manila	PHP	298.8 m	100		•		
Poland							
Novartis Poland Sp. z o.o., Warsaw	PLN	44.2 m	100		•		
Lek S.A., Strykow	PLN	2.6 m	100		•	▼	
Alima-Gerber S.A., Warsaw	PLN	57.1 m	100		•	▼	
Portugal					•		
Novartis Portugal SGPS Lda., Sintra	EUR	500,000	100				
Novartis Fortugal SOLO Laa, Sintra	EUR	2.4 m	100	-			
Novartis Consumer Health—Produtos Farmacêuticos e Nutrição	2010		100		*		
Lda., Lisbon	EUR	100,000	100		٠		
	2010	100,000	100		•		
Equity interest $\%$ — above 50% and up to 100% of the voting ri	ahts_ful	lly consolide	ated.				

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated; — above 20% and up to 50% of the voting rights—investment in associated company—equity method accounting.

<sup>(1)</sup> Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

	Share/paid-in capital <sup>(1)</sup>		Equity Interest %	Activi	ties	
Puerto Rico         Ex-Lax, Inc., Humacao         Gerber Products Company of Puerto Rico, Inc., Carolina	USD USD	10,000 100,000	100 100	٠	<b>*</b>	
Russian Federation Novartis Pharma ZAO, Moscow	RUR	17.5 m	100	٠		
Singapore Novartis Institute for Tropical Diseases Pte Ltd., Singapore	SGD	2,004	100			
Slovenia Lek Pharmaceuticals d.d., Ljubljana	SIT	11.6 bn	100	• •	▼	
South Africa Novartis South Africa (Pty) Ltd., Spartan/Johannesburg	ZAR	86.4 m	100	•	▼	
South Korea Novartis Korea Ltd., Seoul	KRW	24.5 bn	99	•		
Spain Novartis Farmacéutica, S.A., Barcelona	EUR EUR	63.0 m 270,450	100 100	• •	▼	
Barcelona	EUR EUR EUR EUR	9.3 m 876,919 266,860 1.4 m	100 100 97 100	* * *	•	▲ ▲
Sweden Novartis Sverige Participations AB, Täby/Stockholm Novartis Sverige AB, Täby/Stockholm	SEK SEK SEK	51.0 m 5.0 m 2.5 m	100 100 100	•		

Equity interest % — above 50% and up to 100% of the voting rights-fully consolidated;

- above 20% and up to 50% of the voting rights-investment in associated company-equity method accounting.

<sup>(1)</sup> Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

	Share/paid-in capital <sup>(1)</sup>		Equity Interest %		Activi	ties	
Switzerland							
Novartis International AG, Basel	CHF	10.0 m	100				
Novartis Holding AG, Basel	CHF	100.2 m	100				
Novartis Securities AG, Basel	CHF	50.0 m	100				
Novartis Research Foundation, Basel	CHF	29.3 m	100				
Foundation Novartis for Management Development, Basel	CHF	100,000	100				
Roche Holding AG, Basel	CHF	160.0 m	33		•	$\bullet$	
Novartis Pharma AG, Basel	CHF	350.0 m	100		•	▼	
Novartis Pharma Services AG, Basel	CHF	50,000	100		•		
Novartis Pharma Schweizerhalle AG, Schweizerhalle	CHF	18.9 m	100			$\bullet$	
Novartis Pharma Stein AG, Stein	CHF	251,000	100			▼	
Novartis Pharma Schweiz AG, Bern	CHF	5.0 m	100		•		
Novartis Consumer Health S.A., Nyon	CHF	30.0 m	100		•	$\bullet$	
Novartis Consumer Health Schweiz AG, Bern	CHF	250,000	100		•		
Novartis Animal Health AG, Basel	CHF	101,000	100		•	$\bullet$	
Novartis Centre de Recherche Santé Animale S.A., St.Aubin	CHF	250,000	100				
Novartis Nutrition AG, Bern	CHF	40.0 m	100				
SANUTRI AG, Bern	CHF	31.6 m	97				
CIBA Vision AG, Embrach	CHF	300,000	100	•	•		
Taiwan							
Novartis (Taiwan) Co., Ltd., Taipei	TWD	170.0 m	100		•	▼	
Thailand							
Novartis (Thailand) Limited, Bangkok	THB	230.0 m	100		•		
Turkey							
Novartis Saglik, Gida ve Tarim Ürünleri Sanayi ve Ticaret A.S., Istanbul	TRL	98.0 tr	100		٠	•	
Equity interest $\%$ — above 50% and up to 100% of the voting ri	ghts—ful	lly consolida	ited;				

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated;

— above 20% and up to 50% of the voting rights—investment in associated company—equity method accounting.

(1) Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

#### 31. Principal Group subsidiaries and associated companies as at December 31, 2004 (Continued)

	Share/paid-in capital <sup>(1)</sup>				Activities		
USA							
Novartis Corporation, Florham Park, NJ	USD	72.2 m	100				
Novartis Finance Corporation, New York, NY	USD	1.7 bn	100				
Novartis Pharmaceuticals Corporation, East Hanover, NJ	USD	5.2 m	100		•	▼	
Novartis Ophthalmics, Inc., Duluth, GA	USD	1,000	100		•	▼	
Novartis Institutes for BioMedical Research, Inc., Cambridge,							
MA	USD	1	100				
Novartis Institute for Functional Genomics, Inc., San Diego, CA .	USD	1,000	100				
Chiron Corporation, Emeryville, CA	USD	1.9 m	42		•	▼	
Idenix Pharmaceuticals, Inc., Cambridge, MA	USD	47,954	57				
Sandoz Inc., Princeton, NJ	USD	25,000	100		•	▼	
Lek Pharmaceuticals, Inc., Wilmington, NC	USD	200,000	100		•		
Novartis Consumer Health, Inc., Parsippany, NJ	USD	0(2)	100		•	▼	
Novartis Animal Health US, Inc., Greensboro, NC	USD	100	100		•	▼	
Novartis Nutrition Corporation, Minneapolis, MN	USD	50,000	100		•	▼	
Novartis Medical Health, Inc., Minneapolis, MN	USD	1,000	100		•		
Gerber Products Company, Fremont, MI	USD	10	100		•	▼	
Gerber Life Insurance Company, White Plains, NY	USD	2.5 m	100		•		
CIBA Vision Corporation, Duluth, GA	USD	301.3 m	100		•	▼	
Venezuela							
Novartis de Venezuela, S.A., Caracas	VEB	1.4 bn	100		٠		

In addition, the Group is represented by subsidiaries, associated companies or joint ventures in the following countries:

Algeria, Cayman Islands, Costa Rica, Dominican Republic, Guatemala, the former Yugoslav Republic of Macedonia, Morocco, Nigeria, Peru, Romania, Serbia and Montenegro and Uruguay.

Equity interest % — above 50% and up to 100% of the voting rights—fully consolidated;

above 20% and up to 50% of the voting rights—investment in associated company—equity method accounting.

(1) Share/paid-in capital may not reflect the taxable share/paid-in capital amount and does not include any paid-in surplus.

<sup>(2)</sup> Shares of no par value.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP)

The Group's consolidated financial statements have been prepared in accordance with IFRS, which as applied by the Group, differs in certain significant respects from US GAAP. The effects of the application of US GAAP to net income and equity are set out in the tables below:

	Notes	2004	2003	2002
		(\$ millions)	(\$ millions)	(\$ millions)
Net income under IFRS		5,767	5,016	4,725
US GAAP adjustments:				
Purchase accounting: Ciba-Geigy	а	(366)	(339)	(294)
Purchase accounting: other acquisitions	b	17	(175)	(298)
Purchase accounting: IFRS goodwill amortization .	с	170	172	140
Available-for-sale securities and derivative				
financial instruments	d	(183)	(240)	(273)
Pension provisions	e	(6)	(18)	27
Share-based compensation	f	(326)	(273)	(120)
Consolidation of share-based employee				
compensation foundation	g	(4)	(3)	(20)
Deferred taxes	h	100	(63)	(93)
In-process research and development	i	(55)	(260)	(11)
Reversal of currency translation gain	j	(301)		
Other	1	13	(20)	(95)
Deferred tax effect on US GAAP adjustments		163	(9)	141
Net income under US GAAP		4,989	3,788	3,829
Basic earnings per share under US GAAP (\$) $\ldots$		2.12	1.59	1.58
Diluted earnings per share under US GAAP ()		2.11	1.57	1.55

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

	Notes	December 31, 2004	December 31, 2003
		(\$ millions)	(\$ millions)
Equity under IFRS		33,783	30,429
US GAAP adjustments:			
Purchase accounting: Ciba-Geigy	а	3,049	3,131
Purchase accounting: other acquisitions	b	2,803	2,808
Purchase accounting: IFRS goodwill amortization	с	554	327
Available-for-sale securities and derivative financial			
instruments	d	(64)	
Pension provisions	e	1,346	1,209
Share-based compensation	f	(129)	(96)
Consolidation of share-based employee compensation			
foundation	g	(864)	(728)
Deferred taxes	h	(510)	(609)
In-process research and development	i	(1,489)	(1,338)
Minimum Pension Liability	k	(501)	(37)
Other	1	(45)	(56)
Deferred tax effect on US GAAP adjustments		168	(162)
Equity under US GAAP		38,101	34,878

## Components of equity in accordance with US GAAP

	December 31, 2004	December 31, 2003
	(\$ millions)	(\$ millions)
Share capital	1,008	1,017
Treasury shares, at nominal value	(154)	(151)
Share premium	1,103	743
Retained earnings	32,178	31,069
Accumulated other comprehensive income:		
Currency translation adjustment	3,561	1,940
Unrealized market value adjustment on available-for-sale securities,		
net of taxes of \$(78) million (2003: \$(62) million)	725	275
Unrealized market value adjustment on cash-flow hedges net of		
taxes of \$5 million (2003: \$7 million)	(20)	7
Minimum pension liability, net of taxes of \$201 million		
(2003: \$15 million)	(300)	(22)
December 31	38,101	34,878

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### Changes in US GAAP equity

	(\$ millions)
January 1, 2002	30,208
Net unrealized market value adjustment	(502)
Increase in share premium related to share-based compensation	17
Associated companies' equity movement	(104)
Foreign currency translation adjustment	4,158
Net income for the year under US GAAP	3,829
Dividends paid	(1,305)
Acquisition of treasury shares	(3,076)
January 1, 2003	33,225
Net unrealized market value adjustment	381
Increase in share premium related to share-based compensation	373
Minimum pension liability	(22)
Associated companies' equity movement	10
Foreign currency translation adjustment	2,735
Net income for the year under US GAAP	3,788
Dividends paid	(1,654)
Acquisition of treasury shares	(500)
Redemption of call and put options on Novartis shares	(3,458)
January 1, 2004	34,878
Net unrealized market value adjustment	397
Increase in share premium related to share-based compensation	334
Minimum pension liability	(278)
Associated companies' equity movement	50
Foreign currency translation adjustment	1,621
Net income for the year under US GAAP	4,989
Dividends paid	(1,888)
Acquisition of treasury shares	(2,002)
December 31, 2004	38,101

#### Notes to the US GAAP Reconciliation

### *a) Purchase accounting: Ciba-Geigy*

The accounting treatment for the 1996 merger of Sandoz and Ciba-Geigy under IFRS is different from the accounting treatment under US GAAP. For IFRS purposes, the merger was accounted under the uniting of interests method, however, for US GAAP, the merger did not meet all of the required conditions of Accounting Principles Board Opinion No. 16 for a pooling of interests and therefore is accounted for as a purchase under US GAAP. Under US GAAP, Sandoz would be deemed to be the acquirer with the assets and liabilities of Ciba-Geigy being recorded at their estimated fair values and the results of Ciba-Geigy being included from December 20, 1996. Under US GAAP, the cost of Ciba-Geigy to Sandoz was approximately \$28.5 billion. All of the purchase price was allocated to identified tangible

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

and intangible assets with a definite useful life. There was therefore no residual goodwill arising from accounting for this transaction.

The components of the equity and income statement adjustments related to the US GAAP purchase accounting adjustment for 2004, 2003 and 2002 are as follows:

		2004			2003			2002		
	Comp	onents to rec	concile	Comp	onents to rec	oncile	Comp	mponents to reconcile		
	Net income	Foreign currency translation adjustment	Equity	Net income	Foreign currency translation adjustment	Equity	Net income	Foreign currency translation adjustment	Equity	
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	
Intangible assets related to marketed										
products	(518)	369	3,972	(478)	472	4,121	(414)	708	4,127	
Property, plant	. ,									
& equipment .	55	(67)	(726)	51	(81)	(714)	44	(115)	(684)	
Inventory		58	627		62	569		83	507	
Other identifiable										
intangibles	(25)	5	53	(25)	9	73	(20)	16	89	
Investments		14	149		15	135		20	120	
Deferred taxes .	122	(95)	(1,026)	113	(120)	(1,053)	96	(179)	(1,046)	
Total										
adjustment	(366)	284	3,049	(339)	357	3,131	(294)	533	3,113	

The intangible assets related to marketed products and other identifiable intangibles are being amortized over 15 and 10 years, respectively.

### b) Purchase accounting: other acquisitions

Prior to January 1, 1995, the Group wrote off all goodwill, being the difference between the purchase price and the aggregate fair value of property, plant & equipment and intangible assets and liabilities acquired in a business combination, directly to equity, in accordance with IFRS existing at that time. The adoption of IAS 22 (revised 1993) required that goodwill was capitalized and amortized, however, did not require prior period restatement. The material component of goodwill recorded directly to equity, under IFRS prior to January 1, 1995, related to the acquisition of Gerber Products in 1994. The net book value of goodwill under US GAAP attributable to Gerber Products was \$2 870 million as of December 31, 2004 and 2003.

In accordance with IAS 22, the difference between the purchase price and the aggregate fair value of property, plant & equipment and intangible assets and liabilities acquired in a business combination is capitalized as goodwill and amortized over its useful life, not to exceed 20 years. Under US GAAP, the difference between the purchase price and fair value of net assets acquired as part of a pre-1995 business combination is also capitalized as goodwill. Effective January 1, 2002, the Group adopted Statement of Financial Accounting Standards No. 142 (SFAS 142), *Goodwill and other Intangible Assets*. SFAS 142

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

requires that all goodwill and other intangible assets existing on implementation on January 1, 2002 are tested for impairment and thereafter are assessed for impairment on an annual basis. From January 1, 2002 goodwill and intangible assets deemed to have an indefinite useful life are no longer amortized on a regular basis. For the purpose of the reconciliation to US GAAP, goodwill was generally amortized through the income statement over an estimated useful life of 20 years up to December 31, 2001. Therefore, there is no amortization charge since 2002 under US GAAP.

In 2004, as a result of adverse changes in the operating environment of certain businesses, or of the decision to divest certain products, in accordance with SFAS 142, non-cash charges of \$42 million were recorded (2003: \$119 million; 2002 \$229 million) for impairments of goodwill and divestments. Gerber goodwill was also reviewed for potential impairments in 2004 however, this did not result in the Group needing to record a charge. The process of evaluating goodwill involves making judgments and estimates relating to the projection and discounting of future cash flows. This evaluation is sensitive to changes in the discount rate. An increase to discount rates is likely to result in a significant impairment charge under US GAAP.

Also included are US GAAP adjustments to the equity method accounting results of Roche and Chiron totaling \$12 million income (2003: \$56 million expense; 2002: \$69 million expense). The impact of the additional impairment charges, the Roche and Chiron adjustments and other adjustments totaling a net income of \$47 million resulted in a \$17 million net income in 2004 (2003: \$175 million net expense; 2002: \$298 million net expense). Note m(x) provides further disclosure regarding impairment under US GAAP.

### c) Purchase accounting: IFRS goodwill amortization

As described above, as of January 1, 2002, goodwill is no longer amortized but only subject to impairment testing under US GAAP. The corresponding reversal of the regular goodwill amortization under IFRS resulted in an additional income in the US GAAP reconciliation of \$170 million (2003: \$172 million; 2002: \$140 million).

### d) Available-for-sale marketable securities and derivative financial instruments

Under IFRS, fair value changes which relate to the underlying movement in exchange rates on available-for-sale debt securities have to be recognized in the income statement. Under US GAAP, SFAS 133 requires the entire movement in the fair value of the securities to be recognized in equity, including any part that relates to foreign exchange movements. This resulted in US GAAP income being reduced by \$181 million (2003: \$228 million expense; 2002: \$53 million income).

Prior to the adoption of IAS 39 from January 1, 2001 in the IFRS consolidated financial statements, investments were stated at the lower of cost or market value on an individual basis. This results in a different amount of unrealized gains or losses being recorded in the separate component of equity under US GAAP compared to IFRS and an additional expense under US GAAP on disposal of available-for-sale securities during 2004 and 2003. This resulted in an additional expense of \$2 million (2003: \$12 million; 2002: \$326 million).

The above differences resulted in an additional US GAAP expense of \$183 million in 2004 (2003: \$240 million; 2002: \$273 million).

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

In 2004, the Group recorded a revaluation to fair value in its equity on privately held companies under IFRS. Under US GAAP such investments have to be accounted for at cost. Accordingly, \$64 million booked in the IFRS equity was reversed.

### e) Pension provisions

Under IFRS, pension costs and similar obligations are accounted for in accordance with IAS 19, *Employee Benefits*. For purposes of US GAAP, pension costs for defined benefit plans are accounted for in accordance with SFAS 87 *Employers' Accounting for Pensions* and the disclosure are presented in accordance with SFAS 132 *Employers' Disclosures about Pensions and Other Post-retirement Benefits*. Differences in the amounts of net periodic benefit costs and the prepaid benefit cost exist due to different transition date rules, pre-1999 accounting rule differences and different provisions for recognition of a prepaid pension asset. Under IFRS the recognition of a prepaid asset is subject to certain limitations, and any unrecognized prepaid pension asset is recorded as pension expense. US GAAP does not allow a limitation on the recognition of prepaid pension assets recorded in the balance sheet.

The following is a reconciliation of the balance sheet and income statement amounts recognized for IFRS and US GAAP for both pension and post-employment benefit plans:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Pension plans:			
Net asset recognized for IFRS	3,349	3,046	2,786
Difference in unrecognized amounts	1,446	1,314	1,196
Net asset recognized for US GAAP	4,795	4,360	3,982
Net periodic pension (cost)/income recognized for IFRS Difference in recognition of actuarial and past service	(198)	(54)	139
amounts	(9)	(35)	19
Net periodic pension (cost)/income recognized for			
US GAAP	(207)	(89)	158
Other post-employment benefit plans:			
Liability recognized for IFRS	(495)	(460)	(421)
Difference in unrecognized amounts	(100)	(105)	(124)
Liability recognized for US GAAP	(595)	(565)	(545)
Net periodic post-employment benefit cost recognized for			
IFRS	(75)	(63)	(54)
amounts	3	17	8
Net periodic post-employment benefit cost recognized for			
US GAAP	(72)	(46)	(46)
Total US GAAP income statement difference on pensions			
and other post-employment benefits	(6)	(18)	

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

The disclosures required by US GAAP are different from those provided under IFRS. On December 23, 2003, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 132 (revised 2003), *Employers' Disclosures about Pensions and Other Post-retirement Benefits, an amendment of FASB Statements No. 87, 88 and 106, and a revision of FASB Statement No. 132*. The following provides the required separate presentation for Swiss and foreign plans under US GAAP:

	Swiss pension plans		Foreign pension plan		
	2004	2003	2004	2003	
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	
Benefit obligation at the beginning of the					
year	9,793	8,569	4,072	3,276	
Service cost	179	137	172	148	
Interest cost	366	358	214	201	
Actuarial gains/(losses)	1,193	240	208	455	
Plan amendments			(41)	15	
Foreign currency translation	1,048	1,093	156	163	
Benefit payments	(659)	(604)	(213)	(186)	
Benefit obligation at the end of the year	11,920	9,793	4,568	4,072	
Fair value of plan assets at the beginning of					
the year	13,218	11,771	2,910	2,594	
Actual return on plan assets	484	571	254	345	
Foreign currency translation	1,348	1,451	69	55	
Employer contributions			207	92	
Employee contributions	45	29	7	10	
Plan amendments			(7)		
Benefit payments	(659)	(604)	(213)	(186)	
Fair value of plan assets at end of year	14,436	13,218	3,227	2,910	
Funded Status	2,516	3,425	(1,341)	(1,162)	
Unrecognized past service costs			(35)	(49)	
Unrecognized net actuarial losses/(gains)	2,699	1,285	956	861	
Net asset/(liability) in the balance sheet $\ldots$	5,215	4,710	(420)	(350)	
Accumulated benefit obligation	11,217	8,248	4,209	3,565	

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

	Swi	iss pension pl	ans	Fore	ign pension p	olans
	2004	2003	2002	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Components of net periodic benefit costs						
Service cost	179	137	139	172	148	138
Interest cost	366	358	379	214	201	173
Expected returns on plan assets	(520)	(613)	(734)	(195)	(183)	(236)
Employee contributions	(45)	(29)	(2)	(7)	(10)	(5)
actuarial (gains)/lossesAmortization of unrecognized past				75	53	(10)
service costs				(32)	27	
Net periodic benefit cost/(income)	(20)	(147)	(218)	227	236	60
Principal actuarial assumptions used	%	%	%	%	%	%
Weighted average assumptions used to determine benefit obligations at the end of year						
Discount rate	3.3	3.8	4.0	5.2	5.7	5.9
Expected rate of salary increase Weighted average assumptions used to determine net periodic pension cost for the year ended	1.5	2.5	2.5	3.6	3.7	3.6
Discount rate	3.8	4.0	4.0	5.5	6.2	6.4
Expected return on plan assets	4.0	5.0	5.5	6.7	8.2	8.4
Expected rate of salary increase	2.5	2.5	2.5	3.6	3.7	3.6

### f) Share-based compensation

The Group does not account for share-based compensation, as it is not required under IFRS. Under US GAAP, the Group applies Accounting Principles Board Opinion No. 25 (APB 25) Accounting for Stock Issued to Employees and related interpretations in accounting for its plans. As described in Note 26, the Group has several plans that are subject to measurement under APB 25. These include the Long-Term Performance Plan, the Leveraged Share Savings Plan, the old and new Swiss Employee Share Ownership Plans (ESOP), the Restricted Share Plan and the US Management ADS Appreciation Cash Plan.

Compensation expense recognized under the Long-Term Performance Plan was \$27 million for the year ended December 31, 2004 (2003: \$29 million; 2002: \$14 million).

The Leveraged Share Savings Plan is considered to be compensatory based on the fair value of the allocated Novartis AG shares. The shares are blocked for a five year period, at which time the bonus taken in shares are matched on a one-for-one basis. Compensation expense recognized under this plan was \$27 million for 2004 (2003: \$16 million; 2002: \$11 million).

The new Swiss Employee Share Ownership Plan (ESOP) is considered to be compensatory based on the fair value of Novartis AG shares at a fixed date. Compensation expense recognized under this plan was \$219 million for the year ended December 31, 2004 (2003: \$176 million; 2002: \$80 million).

The old Swiss ESOP was considered to be compensatory based on the amount of the discount allowed for employee share purchases. Compensation expense was recorded at the grant date and was calculated as the spread between the share price and the strike price on that date. During 2002, the Group

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

sold 406,448 shares to employees, which has resulted in a compensation expense of \$13 million. The discount to the Group's share price was recorded in share premium. The percentage discount to the Group's share price under this plan was 75% in 2002, which was the last year, in which employees could purchase shares under this scheme.

The Restricted Share Plan is considered to be compensatory based on the strike price for the underlying instruments, which is zero at the date of grant. Compensation expense is recorded at the grant date and is calculated as the number of instruments granted, multiplied by the share price on that date. Compensation expense recognized under this plan was \$5 million for the year ended December 31, 2004 (2003: \$5 million; 2002: \$4 million).

The US Management ADS Appreciation Cash Plan is considered to be variable because the final benefit to employees depends on the Group's share price at the exercise date. Compensation expense is recorded at each balance sheet date by estimating the number of rights outstanding multiplied by the spread between the share price on the balance sheet date and the strike price. Compensation expense for this plan was \$21 million for 2004 (2003: \$47 million expense; 2002: \$2 million income). This plan was supplemented in 2001 by the US ADS Incentive Plan which grants options on Novartis ADSs. Disclosures relating to this Plan is included in note m (vii).

The total US GAAP expense of the above items is as follows:

	2004	2003	2002
	(\$ millions)	(\$ millions)	(\$ millions)
Long-Term Performance Plan	27	29	14
Leveraged Share Savings Plan	27	16	11
New Swiss ESOP Plan	219	176	80
Old Swiss ESOP Plan			13
Restricted Share Plan	5	5	4
ADS Appreciation Cash Plan	21	47	(2)
Option grants converted to share grants	27		
Total US GAAP additional compensation expense	326	273	120

### g) Consolidation of share-based compensation foundation

The Group has an employee share participation foundation that settles the obligations of the Group's share-based compensation plans that is not required to be consolidated for IFRS. However, this foundation is consolidated under US GAAP.

The consolidation of this foundation reduces net income by \$4 million (2003: \$3 million; 2002: \$20 million) and US GAAP equity by \$864 million (2003: \$728 million).

### h) Deferred taxes

Under IAS 12 (revised) and US GAAP, unrealized profits resulting from intercompany transactions are eliminated from the carrying amount of assets, such as inventory. In accordance with IAS 12 (revised) the Group calculates the tax effect with reference to the local tax rate of the company that holds the inventory (the buyer) at period-end. However, US GAAP requires that the tax effect is calculated with

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

reference to the local tax rate in the seller's or manufacturer's jurisdiction. The effect of this difference increased US GAAP income in 2004 by \$100 million (2003: \$63 million reduction; 2002: \$93 million reduction) and reduced equity by \$510 million (2003: \$609 million).

#### *i)* In-process research and development (IPR&D)

Under US GAAP, IPR&D is considered to be a separate asset that needs to be written-off immediately following the acquisition as the feasibility of the acquired research and development has not been fully tested and the technology has no alternative future use. Up to March 31, 2004, IFRS did not consider that IPR&D was an intangible asset that could be separately recognized, accordingly it was included in goodwill for IFRS purposes. Under IAS 38 (revised) for all post-March 31, 2004 acquisitions, IPR&D is now separately identified and recorded as an intangible asset subject to annual impairment tests.

During 2004, IPR&D arose on the acquisition of 100% of the shares of Sabex (\$132 million) and Durascan (\$8 million).

During 2003, IPR&D has been identified for US GAAP purposes in connection with acquisitions, principally the acquisition of 51% of the shares of Idenix. All projects of Idenix are under research or development, therefore the full goodwill recorded under IFRS amounting to \$297 million was considered as IPR&D under US GAAP. IPR&D recognized on other acquisitions amounted to \$39 million in 2003.

During 2002, IPR&D arose on the acquisitions of a further 11.4% of the voting shares of Roche (\$123 million), of 99% of the shares of Lek (\$84 million), and of others (\$17 million).

The income booked for the reversal of the amortization of IPR&D recorded under IFRS as a component of goodwill amortization amounted to \$85 million (2003: \$76 million; 2002: \$213 million). The total net IPR&D expense for 2004 was \$55 million (2003: \$260 million; 2002: \$11 million). The impact of IPR&D reduced US GAAP equity by \$1,489 million (2003: \$1,338 million).

#### *j)* Reversal of currency translation gain

During 2004, under IFRS the Group recorded a recycling gain from cumulative translation differences of \$301 million arising from the partial repayment of capital of a subsidiary. US GAAP does not recognize this concept so this gain has been eliminated for US GAAP purposes.

### k) Minimum pension liability

The additional minimum pension liability required under US GAAP reduced equity by \$501 million (2003: \$37 million).

### *l)* Other

There are also differences between IFRS and US GAAP in relation to (1) capitalized interest and capitalized software, (2) LIFO inventory, (3) reversals of inventory provisions. None of these differences are individually significant and they are therefore shown as a combined total.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

m) Additional US GAAP disclosures

### (i) Financial assets and liabilities

Apart from the following exceptions, the US GAAP carrying value of financial assets and liabilities is equal to the IFRS carrying values.

## (ii) Cash, cash equivalents and time deposits

	2004	2003
	(\$ millions)	(\$ millions)
Carrying value of cash and cash equivalents under IFRS	6,083	5,646
Carrying values of time deposits under IFRS (Note 16)	1,353	651
Change due to consolidation of share-based compensation foundation		
under US GAAP	(712)	(650)
Total under US GAAP	6,724	5,647

## (iii) Marketable securities

	2004	2003
	(\$ millions)	(\$ millions)
Carrying values of marketable securities under IFRS (Note 16)	6,623	6,134
Carrying values of other investments under IFRS	1,286	1,076
Marketable securities in share-based compensation foundation		
consolidated under US GAAP	13	16
Total under US GAAP	7,922	7,226

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (iii) Marketable securities (Continued)

The components of available-for-sale marketable securities under US GAAP at December 31, 2004 and 2003 are the following:

	Cost	Gross unrealized gains	Gross unrealized losses	Carrying value and estimated fair value
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
As of December 31, 2004 Available-for-sale securities:				
Equity securities	681	201	(10)	872
Debt securities	6,587	494	(31)	7,050
Total	7,268	<u>695</u>	(41)	7,922
As of December 31, 2003 Available-for-sale securities:				
Equity securities	1,744	209	(293)	1,660
Debt securities	5,299	270	(3)	5,566
Total	7,043	479	(296)	7,226

Proceeds from sales of available-for-sale securities were \$5,915 million and \$6,293 million in 2004 and 2003 respectively. Gross realized gains were \$75 million and \$199 million on those sales in 2004 and 2003 respectively. Gross realized losses were \$228 million and \$115 million on those sales in 2004 and 2003, respectively. The cost used to determine the gain or loss on these sales was calculated using the weighted average method. As at December 31, 2004 there were no (2003: \$258 million) unrealized losses on equity securities that existed for more than 12 months.

The maturities of the available-for-sale debt securities included above at December 31, 2004 are as follows:

	2004
Within one year	(\$ millions) 325
Over one year through five years	
Over five years through ten years	
Over ten years	
Total	7,050

### (iv) Derivative financial instruments

From January 1, 2001, the Group adopted SFAS 133 Accounting for Derivative Instruments and Hedging Activities which as applied by the Group is consistent with IAS 39 as regards accounting for cash flow hedges.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (iv) Derivative financial instruments (Continued)

In 2004 and 2003, there were no gains and losses in accordance with US GAAP on options settled in Novartis shares that require a net cash settlement (2002: \$123 million of gains).

#### (v) Non-derivative financial instruments

The US GAAP carrying values are equivalent to the IFRS carrying values for all non-derivative financial assets and liabilities with the exception of privately held companies that are valued at costs under US GAAP. Non-derivative financial assets consist of cash and cash equivalents, time deposits, and marketable securities. Non-derivative liabilities consist of commercial paper, bank or other short-term financial debts, and long-term debt.

The carrying amount of cash and cash equivalents, time deposits, commercial paper, and bank and other short-term financial debts approximates their estimated fair values due to the short-term nature of these instruments. The fair values of marketable securities are estimated based on listed market prices or broker or dealer price quotes. The fair value of long-term debt is estimated based on the current quoted market rates available for debt with similar terms and maturities.

The estimated fair values of the long and short-term financial debt are provided in notes 18 and 20 to the IFRS consolidated financial statements.

### (vi) Earnings per share

As discussed in item g) above, in the past, the Group established the Novartis Foundation for Employee Participation to assist the Group in meeting its obligations under various employee benefit plans and programs. This Foundation supports existing, previously approved employee benefit plans.

For US GAAP purposes, the Group consolidates this Foundation. The cost of Novartis AG shares held by the Foundation is shown as a reduction of shareholders' equity in the Group's US GAAP balance sheet.

Any dividend transactions between the Group and the Foundation are eliminated, and the difference between the fair value of the shares on the date of contribution to the Foundation and the fair values of the shares at December 31, is included in consolidated retained earnings. Shares held in the Foundation

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

### (vi) Earnings per share (Continued)

are not considered outstanding in the computation of US GAAP earnings per share. The consolidation of this entity had the following impact on basic and diluted earnings per share:

	2004	2003	2002
Basic earnings per share:			
Net income under US GAAP (\$ millions)	4,989	,	
Weighted average number of shares in issue under IFRS Weighted average number of treasury shares due to consolidation of the employee share participation		2,473,522,565	
foundation under US GAAP Weighted average number of shares in issue under	( ) ) )	(93,430,809)	
US GAAP	2,355,490,272	2,380,091,756	2,418,147,195
Basic earnings per share under US GAAP (\$)	2.12	1.59	1.58
	2004	2003	2002
Diluted earnings per share:			
<b>Net income under US GAAP (\$ millions)</b> Elimination of interest expense on convertible debt (net	4,989	3,788	3,829
of tax effect)			3
Net income used to determine diluted earnings per share	4,989	3,788	3,832
Weighted average number of shares in issue under IFRS Adjustment for assumed conversion of convertible debt .	2,447,954,717	2,473,522,565	2,515,311,685
Call options on Novartis shares		27,446,092	54,891,036
Adjustment for other dilutive share options Weighted average number of treasury shares due to consolidation of the employee share participation	11,917,258	4,346,940	2,264,236
foundation under US GAAP	(92,464,445)	(93,430,809)	(97,164,490)
Weighted average number of shares for diluted earnings			
per share under US GAAP	2,367,407,530	2,411,884,788	2,475,302,467
Diluted earnings per share under US GAAP (\$)	2.11	1.57	1.55

### (vii) Pro forma earnings per share

Statement of Financial Accounting Standards No. 123 (SFAS 123) Accounting for Stock-Based Compensation established accounting and disclosure requirements using a fair-value based method of accounting for share-based employee compensation. Had the Group accounted for share options in

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

### (vii) Pro forma earnings per share (Continued)

accordance with SFAS 123, net income and earnings per share would have been the pro forma amounts indicated below:

	2004	2003	2002
Net income under US GAAP (\$ millions):			
As reported	4,989	3,788	3,829
Stock-based employee compensation cost included in the determination of net income	326	273	120
Stock-based employee compensation cost that would have been included in the determination of net income if the			
fair value based method had been applied to all awards	(542)	(459)	(210)
Pro forma	4,773	3,602	3,739
Earnings per share (\$):			
As reported:			
Basic	2.12	1.59	1.58
Diluted	2.11	1.57	1.55
Pro forma:			
Basic	2.03	1.51	1.55
Diluted	2.02	1.49	1.51

The weighted average assumptions used in determining the fair value of option grants were as follows:

	2004	2003	2002
Dividend yield	1.8%	1.8%	1.8%
Expected volatility	23.1%	24.0%	24.0%
Discount rate	3.6%	4.0%	4.0%
Expected life	10 yrs	9 yrs	9 yrs

These pro forma effects may not be representative of future amounts since the estimated fair value of share options on the date of grant is amortized to expense over the vesting period and additional options may be granted in future years.

### (viii) Deferred tax

The deferred tax asset less valuation allowance at December 31, 2004 and 2003 comprises \$1,265 million and \$1,590 million of current assets and \$1,456 million and \$987 million of non-current assets respectively. The deferred tax liability at December 31, 2004 and 2003 comprises \$1,289 million and \$1,202 million of current liabilities and \$3,993 million and \$3,935 million of non-current liabilities respectively.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

### (ix) Foreign currency translation

The Group has accounted for operations in highly inflationary economies in accordance with IAS 21 (revised) and IAS 29. The accounting under IAS 21 (revised) and IAS 29 complies with Item 18 of Form 20-F and is different from that required by US GAAP.

#### (x) US GAAP goodwill

Goodwill is the only intangible asset within the Group which is not subject to amortization under US GAAP. All goodwill components were tested for impairment during 2004. The fair values of the businesses were determined using the expected present values of future cash flows.

The Group estimates that the aggregate amortization expense for intangibles subject to amortization for each of the five succeeding financial years will not materially differ from the current aggregate amortization expense

The changes in the carrying amount of goodwill for the years ended December 31, 2004 and 2003 are as follows:

		Consumer	<b>Consumer Health Business Units</b>						
	Pharmaceuticals Division	Health Division	Sandoz	OTC		Medical Nutrition		CIBA Vision	Total
		(\$ millions)							
January 1, 2003	67	<b>4,399</b> 7	921	20	176	<b>55</b> 7	2,920	307	<b>4,466</b> 7
identified intangible assets Impairment losses	(12)	(423) (179)	(425) (170)		(8)	2		(1)	(423) (191)
Goodwill written off related to disposal of business Consolidation changes	(35)	(5)			(5)				(40)
Translation effects	2	116	102	4	9	6	(5)		118
December 31, 2003	22	<b>3,915</b> 535	<b>428</b> 352	24	172	<b>70</b> 183	2,915	306	<b>3,937</b> 535
identified intangible assets Impairment losses Goodwill written off related to		6 (106)	6 (106)	(2)	2				6 (106)
disposal of business	1	(13) 80	$(11) \\ 63$	3	(1) 9	3	1	$(1) \\ 1$	(13) 81
December 31, 2004	23	4,417	732	25	182	256	2,916	306	4,440

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (xi) Details to significant capitalized trademarks and product and patent rights

	Gross carrying value Dec. 31, 2004	Accumulated amortization Dec. 31, 2004	Net carrying value Dec. 31, 2004	Net carrying value Dec. 31, 2003
	(\$ millions)	(\$ millions)	(\$ millions)	(\$ millions)
Famvir	1,860	(559)	1,301	1,360
Voltaren	2,011	(955)	1,056	1,095
Tegretol	653	(261)	392	385
Other pharmaceutical products	4,255	(2,131)	2,124	2,777
Total Pharmaceuticals Division	8,779	(3,906)	4,873	5,617
Sandoz	864	(142)	722	561
ОТС	155	(55)	100	100
Animal Health	500	(238)	262	274
Medical Nutrition	25	(23)	2	7
CIBA Vision	540	(223)	317	336
Total Consumer Health Division	2,084	(681)	1,403	1,278
Total	10,863	(4,587)	6,276	6,895

Novartis usually applies the straight-line amortization method although there can be exceptions as indicated below. For Pharmaceutical Division products the patent life generally reflects the useful life although in certain circumstances a value is also given to the non-patent protected period. For other segments the maximum useful life used is 20 years.

#### Famvir

The value of Famvir has been bifurcated, with the majority of the value assigned to its sales under patent protection. This portion is amortized over the remaining patent life until 2010.

The remainder is amortized over an additional 10 year period representing its value as a branded non-patent protected product. This amortization charge is half of the amount during the patent period.

### Voltaren

Voltaren is off-patent in the US and many other countries. Voltaren as a branded product has had approximately \$600 million of sales outside of the US in each of the past three years. Novartis applies a straight-line amortization period and the useful life ends in 2011.

#### Tegretol

Tegretol is off-patent. Tegretol as a branded product has had sales of approximately \$350 million in each of the past three years. Novartis applies a straight-line amortization period and the useful life ends in 2011.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (xii) Effect of New Accounting Pronouncements: International Financial Reporting Standards

In December 2003, International Accounting Standards (IAS) were amended as the IASB released revised IAS 32, *Financial Instruments: Disclosure and Presentation* and IAS 39, *Financial Instruments: Recognition and Measurement*. These standards replace IAS 32 (revised 2000), and supersedes IAS 39 (revised 2000), and must be applied for annual periods beginning on or after January 1, 2005.

In December 2003, as a part of the IASB's project to improve International Accounting Standards, the IASB released revisions to the following standards that supersede the previously released versions of those standards: IAS1, *Presentation of Financial Statements;* IAS 2, *Inventories;* IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors;* IAS 10, *Events after the Balance Sheet Date;* IAS 16, *Property, Plant and Equipment;* IAS 17, *Leases;* IAS 21, *The Effects of Changes in Foreign Exchange Rates;* IAS 24, *Related Party Disclosures;* IAS 27, *Consolidated and Separate Financial Statements;* IAS 28, *Investments in Associates;* IAS 31, *Interests in Joint Ventures;* IAS 33, *Earnings per Share* and IAS 40, *Investment Property.* The revised standards must be applied for annual periods beginning on or after January 1, 2005. During 2004 the following International Financial Reporting Standards (IFRS) were issued: *IFRS 2, Share-Based Payments; IFRS 3, Business Combinations; IFRS 4, Insurance Contracts; IFRS 5, Non-Current Assets Held for Sale and Discontinued Operations* and *IFRS 6, Exploration for and Evaluation of Mineral Resources.* The following is a summary of the material impact on the Group's consolidated financial statements expected from applying these revised standards.

### a) IAS 39 on Financial Instruments: Cash flow hedges for forecast intragroup transactions

Under IAS 39 (revised) no cash flow hedge accounting is available on forecast intragroup transactions. Any deferral of hedging gains or losss that were included in the 2004 and 2003 consolidated financial statements needs to be reversed.

#### b) Presentation of minority interests to be changed

IAS 1 (revised) requires that minority interests are included in the Group's equity in the consolidated balance sheet and not be shown as a separate category and that it is no longer deducted in arriving at the Group's net income. The effect of this is to increase the Group's equity at January 1, 2005 by \$138 million. Earnings per share will continue to be calculated on the net income attributable solely to the equity holders of Novartis AG.

### c) Presentation of the tax related to associated companies to be changed

IAS 1 (revised) requires that the tax related to the result of associated companies is no longer included in the Group's tax expense. From January 1, 2005 the Group's share in the results of its associated companies will be included on one income statement line and will be calculated after deduction of their taxes and minority interests.

#### d) IFRS 2 on share-based payments

IFRS 2 comes into force on January 1, 2005 and requires that the fair value of any equity instruments granted to employees or other parties is recognized as an expense. Novartis only uses grants of its equity instruments to compensate its employees. Up to December 31, 2004 the approximate fair value of these equity instruments has been charged to the business operations in the segment reporting but has been

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (xii) Effect of New Accounting Pronouncements: International Financial Reporting Standards (Continued)

off-set by a matching income in Corporate other income & expense. Therefore, no pre-tax operating income charge was ultimately recognized in the Group's IFRS consolidated financial statements.

From January 1, 2005 Novartis will calculate the fair value of the granted options using a variant of the lattice binominal approach. The amounts will be charged to income over the relevant vesting periods, adjusted to reflect actual and expected levels of vesting. As permitted by IFRS 2, Novartis will restate in 2005 its prior year audited historical consolidated financial statements to reflect the cost of grants awarded since the effective date of IFRS 2 on November 7, 2002. The Group is in the process of assessing what impact the pronouncement will have on its consolidated financial statements.

The Group does not anticipate that there will be any material additional tax benefit from this change in accounting policy.

#### e) SIC-12 change relating to consolidation of equity compensation plans

Changes to the Standing Interpretations Committee SIC-12 come into force on January 1, 2005 which require the consolidation of equity compensation plans. Prior to this change there was no requirement under IFRS to consolidate these plans.

The effect of consolidation of these plans from January 1, 2005 will be to reduce the Group's financial assets and equity by \$864 million and to increase its treasury shares by 87.3 million. This change will have a corresponding impact on the Group's earnings per share (EPS) calculation prepared under IFRS. The equity compensation plan is already consolidated under US GAAP and the additional treasury shares are included in the US GAAP EPS calculation.

## f) IFRS 3 on business combinations and related goodwill amortization

Under IFRS 3, with effect from January 1, 2005, goodwill is considered to have an indefinite life and is not amortized, but is subject to annual impairment testing. This relates not only to goodwill that has been separately identified and recorded in the Divisions' operating balance sheets but also to the goodwill that is embedded in the equity accounting of associated companies. Additional goodwill of \$352 million recognized on transactions consummated after March 31, 2004 is already subject to the new accounting policy and has not been amortized.

During 2004, the Group incurred \$262 million of goodwill amortization expense. Under IFRS 3, such amortization will not be recorded.

## g) IAS 38 revised on intangible assets

Under IAS 38 (revised), Novartis is required to adopt changes to accounting for intangible assets at the same time as it adopts IFRS 3. The following are the principal accounting policy changes.

• A cost needs to be allocated to In-Process Research & Development (IPR&D) as part of the process of allocating the purchase price of a newly acquired business combination. This amount needs to be recorded separately from goodwill and must be assessed for impairment on an annual basis. Once a project included in IPR&D has been successfully developed and is available for use it needs to be amortized over its useful life. Previously, IPR&D was included under goodwill for

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (xii) Effect of New Accounting Pronouncements: International Financial Reporting Standards (Continued)

IFRS purposes but not for US GAAP accounting purposes, where it was separately recognized and immediately expensed. As required by the transitional rules, IPR&D has already been separately capitalized for IFRS purposes for all post-March 31, 2004 acquisitions.

 Acquired R&D assets, such as those related to up-front and milestone payments also need to be capitalized as intangible assets, even if it is uncertain as to whether the R&D will ultimately be successful in producing a saleable product. Previously intangible assets were only recognized if they were acquired after FDA or similar regulatory body approval. Under US GAAP, acquired R&D assets that have not received regulatory approval will continue to be immediately expensed.

The Group is in the process of assessing what impact the pronouncement will have on its consolidated financial statements.

#### (xiii) Effect of New Accounting Pronouncements: US GAAP

In December 2003, the *Medicare Prescription Drug, Improvements and Modernization Act of 2003* (the Medicare Act) was approved in the United States. The Medicare Act provides for two new prescription drug benefit features under Medicare. The Group provides post-retirement benefits to its United States employees so the benefits provided are impacted by the Medicare Act. SFAS 106, *Employers' Accounting for Post-retirement Benefits Other Than Pensions,* requires that enacted changes in the law that take effect in future periods and that will affect the future level of benefit coverage be considered in the current period measurements for benefits to be borne by the Group by \$7 million in 2004. The effect of this change in estimate is included in the December 31, 2004 liability for other post-employment benefits.

FIN 46 *Consolidation of Variable Interest Entities* was effective for Novartis starting January 1, 2004. The Group has concluded that this had no impact on the consolidated financial statements.

In March 2004, the EITF reached consensus on Issue No. 03-01, "The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments" ("EITF 03-01"). EITF 03-01 provides guidance on other-than-temporary impairment models for marketable debt and equity securities and non-marketable securities accounted for under the cost method. On September 30, 2004, the FASB issued FSP 03-01-1, Effective Date of Paragraphs 10-20 of EITF Issue 03-01, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments, delaying the effective date for the recognition and measurement guidance in EITF 03-01, until certain implementation issues are addressed and a final FSP is issued. The disclosure requirements in EITF 03-01 remain effective. In light of the deliberations on EITF 03-01, the Group changed its policy for the accounting for other-than temporary impairments, such that all available-for-sale equity securities with unrealized losses at the balance sheet date are assessed for impairment (previously when the fair value was 50% of cost for a sustained period of six months). The effect of the change in estimate, which has also been adopted in the Group's IFRS consolidated financial statements, has been to record additional impairment charges on the available-for-sale equity securities of \$101 million. Please also refer to Note 1 "Accounting Policies".

In November 2004, the FASB issued FASB Statement No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4, clarifying the existing requirements in ARB No. 43 by adopting language similar to that used in IAS 2.

# 32. Significant Differences Between IFRS and United States Generally Accepted Accounting Principles (US GAAP) (Continued)

#### (xiii) Effect of New Accounting Pronouncements: US GAAP (Continued)

The guidance is effective for inventory costs incurred during fiscal years beginning after June 15, 2003. The adoption of FAS 151 will not have an impact on the Group's consolidated results of operation or financial position, since the key elements are already utilized in the Group's IFRS and US GAAP consolidated financial statements.

In December 2004, the FASB published FASB Statement No. 123 (revised 2004). *Share-Based Payments*. This provides guidance on how companies must recognize the compensation cost relating to share-based payment transactions in their financial statements. It will require companies to recognize a compensation cost for the value of options granted in exchange for employee services, based on the grant date fair value of those instruments. FASB No. 123(revised) is effective for public entities as of the beginning of the first interim or annual reporting period that begins after June 15, 2005, however early application is possible. Novartis intends to adopt this revised standard from January 1, 2005.

The Group is in the process of assessing what impact the pronouncement will have on its consolidated financial statements.

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