NOVARTIS AG
Form 20-F
January 28, 2009

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As filed with the Securities and Exchange Commission on January 28, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 20-F

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

OR

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2008

OR

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

OR

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

Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

Lichtstrasse 35
4056 Basel, Switzerland

(Address of principal executive offices)

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

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

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

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

None

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

None

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

2,264,852,842 shares

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

Yes ý No o

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

Yes o No ý

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

Yes ý No o

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

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

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

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

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 o

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

Yes o No ý

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INTRODUCTION 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, 2008 and are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). 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 the European Union (EU) are to the European Union and its 27 member states and references to "Americas" are to North, Central (including the Caribbean) and South America, unless the context otherwise requires; references to "ADS" or "ADSs" are to Novartis American Depositary Shares; references to "associates" are to employees of our affiliates; references to the "FDA" are to the US Food and Drug Administration. All product names appearing in italics are trademarks licensed to or owned by Group companies. Product names identified by a "®" or a " " are trademarks that are not licensed to or owned by the Group. 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.

FORWARD LOOKING STATEMENTS

This Form 20-F contains certain "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which can be identified by the use of forward-looking terminology such as "will" or "expected", or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products, or potential future sales or earnings of the Novartis Group or any of its divisions or business units; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for existing products in any market, or that such products will achieve any particular revenue levels. Nor can there be any guarantee that the Novartis Group, or any of its divisions or business units, will achieve any particular financial results. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection, including the uncertainties involved in the US litigation process; competition in general; government, industry, and general public pricing and other political pressures; and the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet. Some of these factors are discussed

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in more detail herein, including under "Item 3. Key Information 3.D. Risk factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects." Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Form 20-F as anticipated, believed, estimated or expected. We provide the information in this 20-F as of the date of its filing. We do not intend, and do not assume any obligation, to update any information or forward looking statements set out in this Form 20-F.

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PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3.A Selected Financial Data

The selected financial information set out below has been extracted from our consolidated financial statements prepared in accordance with IFRS as issued by the IASB. Our consolidated financial statements for the years ended December 31, 2008, 2007 and 2006 are included in "Item 18. Financial Statements" in this Form 20-F.

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

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

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	Year Ended December 31,				
	2008	2007	2006	2005	2004[1]
	($ millions, except per share information)				
INCOME STATEMENT DATA					
Net sales from continuing operations	**41,459**	**38,072**	**34,393**	**29,446**	**25,685**
Operating income from continuing operations	**8,964**	**6,781**	**7,642**	**6,507**	**5,835**
Income from associated companies	441	412	264	193	68
Financial income	384	531	354	461	486
Interest expense	(290)	(237)	(266)	(294)	(261)
Income before taxes from continuing operations	**9,499**	**7,487**	**7,994**	**6,867**	**6,128**
Taxes	(1,336)	(947)	(1,169)	(986)	(962)
Net income from continuing operations	**8,163**	**6,540**	**6,825**	**5,881**	**5,166**
Net income from discontinued operations	70	5,428	377	260	214
Group net income	**8,233**	**11,968**	**7,202**	**6,141**	**5,380**
Attributable to:					
Shareholders of Novartis AG	8,195	11,946	7,175	6,130	5,365
Minority interests	38	22	27	11	15
Operating income from discontinued operations (including divestment gains)	70	6,152	532	398	317
Basic earnings per share ($):					
Continuing operations	3.59	2.81	2.90	2.52	2.19
Discontinued operations	0.03	2.34	0.16	0.11	0.09
Total	3.62	5.15	3.06	2.63	2.28
Diluted earnings per share ($):					
Continuing operations	3.56	2.80	2.88	2.51	2.18
Discontinued operations	0.03	2.33	0.16	0.11	0.09
Total	3.59	5.13	3.04	2.62	2.27
Cash dividends[2]	3,345	2,598	2,049	2,107	1,896
Cash dividends per share in CHF[3]	2.00	1.60	1.35	1.15	1.05
Operating income from continuing operations earnings per share ($):					
Basic	3.96	2.93	3.26	2.79	2.48
Diluted	3.92	2.91	3.24	2.78	2.46

(1) We adopted a number of new International Financial Reporting Standards from January 1, 2005, not all of which required retrospective application. Data for 2004 is therefore not comparable with 2008, 2007, 2006 and 2005.

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

(3) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2008 will be proposed to the Annual General Meeting on February 24, 2009 for approval.

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	Year Ended December 31,				
	2008	2007	2006	2005	2004
			($ millions)		
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial instruments	6,117	13,201	7,955	10,933	13,892
Inventories	5,792	5,455	4,498	3,725	3,558
Other current assets	8,972	8,774	8,215	6,785	6,470
Non-current assets	57,418	48,022	46,604	36,289	28,568
Assets held for sale related to discontinued operations			736		
Total assets	**78,299**	**75,452**	**68,008**	**57,732**	**52,488**
Trade accounts payable	3,395	3,018	2,487	1,961	2,020
Other current liabilities	13,109	13,623	13,540	13,367	9,829
Non-current liabilities	11,358	9,415	10,480	9,240	9,324
Liabilities related to discontinued operations			207		
Total liabilities	**27,862**	**26,056**	**26,714**	**24,568**	**21,173**
Issued share capital and reserves attributable to shareholders of Novartis AG	50,288	49,223	41,111	32,990	31,177
Minority interests	149	173	183	174	138
Total equity	**50,437**	**49,396**	**41,294**	**33,164**	**31,315**
Total liabilities and equity	**78,299**	**75,452**	**68,008**	**57,732**	**52,488**
Net assets	50,437	49,396	41,294	33,164	31,315
Outstanding share capital	820	815	850	848	849
Total outstanding shares (millions)	2,265	2,264	2,348	2,336	2,338

Cash Dividends per Share

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

Year Earned	Month and Year Paid	Total Dividend per share (CHF)	Total Dividend per ADS ($)
2004	March 2005	1.05	0.93
2005	February 2006	1.15	0.87
2006	March 2007	1.35	1.11
2007	February 2008	1.60	1.41
2008[1]	February 2009	2.00	1.88[2]

(1) Dividend to be proposed at the Annual General Meeting on February 24, 2009 and to be distributed February 27, 2009.

(2)

Translated into US dollars at the 2008 period end rate of $0.94 to the Swiss franc. This translation is an example only, and should not be construed as a representation that the Swiss franc amount represents, or has been or could be converted into US dollars at that or any other rate.

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Exchange Rates

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Reuters Market System. The exchange rate in effect on January 21, 2009, as found on Reuters Market System, was CHF 1.00 = $0.87.

Year ended December 31, ($ per CHF)	Period End	Average[1]	Low	High
2004	0.88	0.81	0.76	0.88
2005	0.76	0.80	0.75	0.88
2006	0.82	0.80	0.76	0.84
2007	0.88	0.83	0.80	0.91
2008	0.94	0.93	0.82	1.02
Month end,				
August 2008			0.90	0.95
September 2008			0.88	0.92
October 2008			0.86	0.89
November 2008			0.82	0.87
December 2008			0.82	0.96
January 2009[2]			0.87	0.94

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

(2) Through January 21, 2009.

3.B Capitalization and Indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk Factors

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

Risks Facing Our Business

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

Our Pharmaceuticals Division's products are generally protected by patent rights, which are intended to provide us with exclusive rights to market the patented products. However, those patent rights are of varying strengths and durations. Loss of market exclusivity for one or more important products whether due to patent expiration, generic challenges or other reasons could have a material adverse effect on our

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results of operations. The introduction of a generic version of a branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at sharply lower prices. The pharmaceuticals industry is confronted by a continuing high level of patent expirations, with products representing approximately $24 billion in combined annual sales facing patent expiry in 2009, similar to levels seen in 2007 and 2008, according to IMS Health. In addition, generic manufacturers are increasingly conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement, before final resolution of legal proceedings.

In 2008, sales of four Novartis Pharmaceuticals Division products *Lotrel* (high blood pressure)*Lamisil* (fungal infections), *Trileptal* (epilepsy) and *Famvir* (viral infections) continued to lose sales following the start of generic competition in the US in 2007. As a result of generic competition, combined net sales for these products declined from $2.6 billion in 2006 to $1.6 billion in 2007 and $536 million in 2008. The sharp reduction in net sales of these products had an adverse effect on the results of operations of our Pharmaceuticals Division in 2007 and 2008.

Four of our five best-selling products, *Diovan* (high blood pressure), *Zometa*, *Femara* (both for cancers), and *Sandostatin* (acromegaly) potentially could face generic competition in the near future in various markets, either in the US or Europe, or both, whether due to patent challenges or the scheduled expiration of patents. In particular, the patent on our top-selling drug, *Diovan*, expires in the major countries of the EU in 2011 and in the US in 2012. In addition, sales of Diovan may begin to erode in 2009 in certain countries in the EU and in 2010 in the US when a competitor product, Cozaar®, goes off-patent. Similarly, zoledronic acid, the active ingredient in *Zometa*, as well as in *Reclast/Aclasta* (osteoporosis), is currently the subject of US patent litigation, with the possibility of an "at risk launch" by one or more generic competitors as early as the end of 2010. *Femara's* patent will expire in 2011 in the US and in major European markets. Patent litigation against a generic manufacturer who challenged the *Femara* patent has been settled. Finally, patents protecting the *Sandostatin LAR* formulation, the long-acting version of *Sandostatin* which represents a majority of our sales, expires in 2010 in major markets outside the US (and in 2014 and beyond in the US). Clearly, the loss of exclusivity of any one of these four products could have a material adverse effect on our business, financial condition and results of operations.

In addition to *Zometa* and *Reclast/Aclasta,* key products of our Pharmaceuticals Division that are the subject of ongoing US patent litigation include *Lescol* (high cholesterol), *Focalin/Ritalin LA* (ADHD) and *Comtan/Stalevo* (Parkinson's disease). The loss of exclusivity of some of these products could have a significant adverse effect on the results of operations of our Pharmaceuticals Division. In addition, *Neoral* (transplantation) and *Voltaren* (pain), which are still among our top ten-selling products with combined net sales of $1.8 billion in 2008, have already encountered generic competition in many markets. As a result, sales from these products may decline significantly in the future, which could have a material adverse effect on our business, financial condition and results of operations.

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

We also rely in all aspects of our businesses on unpatented proprietary technology, know-how, trade secrets and other confidential information, which we seek to protect through various measures including confidentiality agreements with licensees, employees, third party collaborators, or consultants who may have access to such information. If these agreements are breached, our contractual remedies may inadequately cover any losses.

Our business is increasingly affected by pressures on drug pricing.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control spending even more tightly. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging

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environment with very significant pricing pressures. These ongoing pressures include government-imposed industry-wide price reductions, mandatory pricing systems, an increase in imports of drugs from lower cost countries to higher cost countries, shifting of the payment burden to patients through higher co-payments, limiting physicians' ability to choose among competing medicines, mandatory substitution of generic drugs and growing pressure on physicians to reduce the prescribing of patented prescription medicines. We expect these efforts to continue as healthcare payors around the globe in particular government-controlled health authorities, insurance companies and managed care organizations step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price cuts.

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

For more information on pricing controls and on our challenging business environment see "Item 4. Information on the Company Item 4.B Business Overview Pharmaceuticals Price Controls" and "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Factors affecting results of operations Pressure to reduce drug prices and increase access to medicines."

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

We must comply with a broad range of regulatory requirements for the development and marketing of our products. These requirements not only affect our development costs, but also the time required to reach the market and the likelihood of successfully doing so. Stricter regulatory requirements also heighten the risk of withdrawal of existing products by regulators on the basis of post-approval concerns over product safety, which would reduce revenues and could result in product recalls and product liability lawsuits. Even in the absence of regulatory action, concerns about efficacy or safety, whether or not scientifically justified, may cause us to voluntarily cease marketing a product or face declining sales. The development of the post-approval adverse event profile for a product or product class also may have a material adverse effect on the marketing and sale of that product. For more detail on the governmental regulations that affect our business, see the sections headed "Regulation" included in the descriptions of our four operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

Following widely publicized product recalls such as the Merck & Co., Inc. recall of its pain medicine Vioxx® in 2004, health regulators are increasingly focusing on product safety and efficacy as well as on the risk/benefit profile of developmental drugs. This has led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analysis of the trials. As a result, obtaining regulatory approvals has become more challenging for pharmaceutical companies. In addition, maintaining regulatory approvals has become increasingly expensive since companies are being required to gather far more detailed safety and other clinical data on products after approval.

We have suffered setbacks in gaining regulatory approvals for new products, as well as being able to keep products on the market, primarily in the Pharmaceuticals Division. For example, in March 2007, we received a so-called "approvable" letter from the FDA regarding *Galvus* (diabetes), which required us to conduct major additional clinical trials in order to obtain US regulatory approval for the drug. Although

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Galvus was subsequently approved in the EU, a resubmission for US approval is not planned. Separately, in the second half of 2007, *Prexige* (osteoarthritic pain) was withdrawn from the market in Australia and some countries of the EU based on post-marketing reports of serious liver side-effects, including two deaths in Australia, allegedly associated with long-term uses of higher doses of the drug. This product was subsequently withdrawn from remaining markets during 2008.

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

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

Our ability to continue to grow our business and to replace any sales lost due to the end of exclusivity for our products whether through patent expiration, generic challenges, competition from new branded products or changes in regulatory status depends upon the success of our research and development activities in identifying and developing high-potential breakthrough products that address unmet needs, are accepted by patients and physicians, and are reimbursed by payors. To accomplish this, we commit substantial effort, funds and other resources to research and development, both through our own dedicated resources and through various collaborations with third parties. Developing new pharmaceutical products and bringing them to market, however, is a costly, lengthy and uncertain process. In spite of our significant investments, there can be no guarantee that our research and development activities will produce a sufficient number of commercially viable new products.

The pharmaceuticals industry has seen a dearth of regulatory approvals for new drugs in recent years. For example, the FDA approved only 18 entirely new drugs (new molecular entities) in 2007, one of the lowest single-year totals since 1983, when there were 14 new approvals. New product approvals for the industry are expected to remain low in the future following FDA approvals for 24 brand new medicines in 2008, according to IMS Health. These approval levels compare with the average annual approval rate of more than 30 new medicines per year in the period from 1996 to 2004, the year that Vioxx was withdrawn from the market. In addition, many of the new drugs approved in recent years have not been as financially successful as those approved in prior years. This relatively low level in research productivity comes at a time when the worldwide pharmaceuticals industry is estimated to be spending more than $40 billion each year on research and development activities.

The research and development process for a new pharmaceutical product can take up to 15 years, or even longer, from discovery to commercial product launch and with a limited available patent life the longer it takes to develop a product, the less time there will be for us to recoup our development costs. New products need not only undergo intensive preclinical and clinical testing, but also to pass a highly complex, lengthy and expensive approval process. During each stage, there is a substantial risk that we will encounter serious obstacles which will further delay us, or that we will not achieve our goals and, accordingly, may abandon a product in which we have invested substantial amounts of time and money. Similar efforts are required to develop new products in our other divisions, as well, and the same risks apply.

If we are unable to maintain a continuous flow of successful new products and new indications or brand extensions for existing products sufficient to cover our substantial research and development costs and to replace sales lost as older products are displaced by competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations.

In addition, we invest a significant amount of effort and financial resources into research and development collaborations with third parties, organizations that we do not control. Many of these may be small companies that do not have the same resources and development expertise as Novartis. If these third parties fail to meet our expectations, we may lose our investment in the collaborations or fail to

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receive the expected benefits, which could have a material adverse effect on our business, financial condition or results of operations.

The current economic and financial crisis may have a material adverse effect on our results.

Many of the world's largest economies and financial institutions currently face extreme financial difficulty, including a decline in asset prices, liquidity problems and limited availability of credit. It is uncertain how long this crisis will last, but many countries are concerned that their economies may enter a deep and prolonged recession. Such difficult economic times may have a material adverse effect on our revenues, results of operations, financial condition and ability to raise capital. Some of our businesses, including the business units of our Consumer Health Division, may be particularly sensitive to declines in consumer spending. In addition, our Pharmaceuticals, Vaccines and Diagnostics and Sandoz Divisions may not be immune to consumer cutbacks. As reported by IMS Health, after ten years of growth, in the first eight months of 2008 the total number of prescriptions dispensed in the US declined, as compared with the same period in 2007. The current economic and financial crisis appears to be affecting all of the major markets in which we operate. As a result, there is a risk that consumers may cut back on prescription drugs and vaccines, as well as consumer health products, to help cope with hard economic times.

In addition, the financial crisis may cause the value of our investments in our pension plans to decrease, requiring us to increase our funding of those pension plans. The financial crisis may also result in a lower return on our financial investments, and a lower value on some of our assets. For example, our investment in Alcon, Inc. has declined significantly in market value since we acquired it in July 2008. The financial crisis could also negatively impact the cost of financing or our ability to finance the second step of the Alcon acquisition on favorable terms. The impact of the current financial crisis on our future access to various kinds of capital, and the cost of that capital, is not currently predictable.

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

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

In recent years, the industries of which we are a part have become important targets of litigation around the world, especially in the US. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including product liability, commercial, employment and wrongful discharge, antitrust, securities, sales and marketing practices, health and safety, environmental and tax litigation claims, government investigations and intellectual property disputes. As a result, we may become subject to substantial liabilities that may not be covered by insurance. Litigation is inherently unpredictable, and large verdicts sometimes occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations or cash flows.

In addition, our Pharmaceuticals Division frequently defends its patents against challenges by our competitors. Should we fail to successfully defend our patents, we will be faced with generic competition for the relevant products, and a resulting loss of revenue.

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

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would not be infringed by our generic product. As a result, we frequently face patent litigation, and in certain circumstances, we may elect to market a generic product even though patent infringement actions are still pending. Should we elect to proceed in this manner and conduct a "launch at risk," we could face substantial damages if the final court decision is adverse to us.

The CIBA Vision Business Unit of our Consumer Health Division also has been required to defend its patents against frequent challenges by competitors.

Separately, the US affiliates of our Pharmaceuticals and Sandoz Divisions are the subjects of lawsuits brought by private plaintiffs and state and local government entities alleging that they have fraudulently overstated the Average Wholesale Price and "best price," which are, or have been, used by the US federal and state governments in the calculation of, respectively, US Medicare reimbursements and Medicaid rebates. A limited number of similar actions have been brought to trial to date against various pharmaceutical companies, including one against our affiliate in the Pharmaceuticals Division, and in certain instances, substantial damages have been awarded. Recent damage awards are on appeal. Should we fail to successfully defend the cases against us, we could face substantial damages if the final court decision is adverse to us.

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

Governments and regulatory authorities have been stepping up their compliance and law enforcement activities in recent years in key areas, including corruption, marketing practices, antitrust and trade restrictions. Our businesses have been subject, from time to time, to such governmental investigations and information requests by regulatory authorities. For example, we are cooperating with civil and criminal investigations currently being undertaken by the US Attorney's Office into allegations of potential off-label promotion of our epilepsy drug, *Trileptal.* While the outcomes of government and regulatory investigations are unpredictable, they are costly, divert management from our business and may affect our reputation. In some instances, the inherent uncertainty of litigation, the resources required to defend against governmental actions and the risk to reputation as well as of potential exclusion from US federal government reimbursement programs have contributed to decisions by companies in our industry to enter into settlement agreements with governmental, and particularly federal, authorities. Those settlements have involved and may continue to involve large cash payments, including the potential repayment of amounts allegedly obtained improperly and penalties up to treble damages. In addition, settlements of healthcare fraud cases typically involve corporate integrity agreements which are intended to regulate company behavior for a period of years. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

For more detail regarding specific legal matters currently pending against us, see "Item 18. Financial Statements note 19" and "Item 4. Information on the Company 4.B Business Overview Pharmaceuticals Intellectual Property."

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

We regularly review our investments in associated companies for impairment. They are reviewed for impairment whenever there is an indication that an impairment may have occurred. The amount of investments in associated companies on our consolidated balance sheet has increased significantly in recent years, primarily as a result of the recent Alcon acquisition. Impairment testing under IFRS may lead to impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and a detailed analysis of the status of our Alcon investment see "Item 5.A Operating Results Critical Accounting Policies and Estimates

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Investments in Associated Companies and Assessment of Alcon Investment" and "Item 18. Financial Statements note 10".

Similarly, we regularly review our long-lived intangible and tangible assets, including identifiable intangible assets and goodwill, for impairment. Goodwill, acquired research and development and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. The amount of goodwill and other intangible assets on our consolidated balance sheet have increased significantly in recent years, primarily as a result of recent acquisitions. In 2008, for example, we recorded an intangible asset impairment charge of $223 million after we decided not to pursue further development of Pharmaceuticals Division pipeline product *Aurograb.* For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing impact of impairment charges on our results of operations see "Item 5.A Operating Results Critical Accounting Policies and Estimates Impairment of Long-Lived Intangible and Tangible Assets" and "Item 18. Financial Statements note 9".

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

At a time of slowing growth in sales of pharmaceuticals in industrialized countries, many emerging markets have experienced comparatively strong economies, leading to higher proportional growth and an increasing contribution to the industry's global performance. In 2008, Novartis generated approximately 64% (2007: 66%) of our net sales from continuing operations in the world's seven largest developed markets, while the seven leading emerging markets Brazil, China, India, Mexico, Russia, South Korea and Turkey contributed 10% (2007: 9%) of net sales. However, combined net sales in these seven priority emerging markets grew 18% in local currency in 2008, compared to 1% sales growth in local currency in the seven largest developed markets during the same period. As a result of this trend, we have been taking steps to increase our presence in these priority emerging markets and in other emerging markets. For example, in 2007 Novartis announced the creation of a new cross-divisional operation to accelerate growth in small emerging markets, expanding the presence of all of our products in regions that include Northern and Sub-Saharan Africa, Central Asia and parts of Southeast Asia.

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

We may not be able to realize the expected benefits from our anticipated acquisition of a majority interest in Alcon.

In April 2008, we announced an agreement with Nestlé S.A. to acquire a 25% stake in Alcon Inc., a world leader in eye care, including pharmaceutical, surgical and consumer products, with the option of acquiring an additional 52% stake in the company. Under that agreement, we purchased the 25% stake from Nestlé in July 2008 for $10.4 billion. In the optional second step, we have the right to acquire Nestlé's remaining 52% majority stake in Alcon between January 1, 2010, and July 31, 2011, for a fixed price of $181.00 per share, or approximately $28 billion. During this period, Nestlé has the right to require Novartis to buy its remaining stake at a 20.5% premium to Alcon's share price at the time of exercise, but

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not exceeding $181.00 per share. Novartis has no obligation to purchase the remaining 23% of shares held by Alcon minority shareholders.

The Alcon acquisition is intended to enhance the diversification of our product portfolio and to give us access to a high-growth area of the healthcare market. However, there can be no guarantee that the second step of the transaction will be completed or that we will, in fact, achieve majority ownership of Alcon. In addition, even if we do obtain majority ownership of Alcon, there can be no guarantee that the acquisition will be successful, or will result in the expected strategic benefits and synergies with our own eye-related businesses. A failure to complete the acquisition of a majority interest in Alcon, or to realize the expected potential strategic benefits and synergies if it is completed, may have a long-term material adverse effect on our business, financial condition or results of operations.

Our indebtedness could adversely affect our operations.

As of December 31, 2008 we had $2.2 billion of non-current financial debt and $5.2 billion of current financial debt. We may in the future incur additional debt for a variety of reasons including our agreement with Nestlé relating to Alcon, Inc. Our current and future debt requires us to dedicate a portion of our cash flow to service interest and principal payments and may limit our ability to engage in other transactions and otherwise place us at a competitive disadvantage to our competitors that have less debt. We may have difficulty refinancing our existing debt or incurring new debt on terms that we would consider to be commercially reasonable if at all.

We may not be able to realize the expected benefits from our significant investments in biologics.

We believe that recent advances in technologies, particularly new approaches in the analysis of human genome data, could have a fundamental effect on product development and, in turn, on our future results of operations. We are, therefore, making major investments in these technologies and devoting significant resources to building our position in biologic therapies, which now represent approximately 25% of our preclinical research portfolio. For our efforts in this area to be successful, we need to ensure a speedy expansion of our capabilities, expertise and skills in the development, manufacturing and marketing of biological therapies. This, however, poses a number of significant challenges, including intense competition for qualified individuals. See also " An inability to attract and retain qualified personnel could adversely affect our business" below.

In 2007, we formed our Novartis Biologics Unit. To complement internal research and development activities, we also have made significant investments in licensing agreements with specialized biotechnology companies. At the same time, our Sandoz Division is taking steps to expand its expertise in biosimilars (generic versions of biological therapies) and is actively working with regulators to establish appropriate rules for the approval of these types of generic products.

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

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

Our Sandoz Division achieves significant revenue opportunities when it secures exclusivity periods granted for generic products in certain markets particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act. Failure to obtain these market exclusivities could have an adverse effect on the success of Sandoz. In addition, the division faces intense competition from branded pharmaceuticals companies, which commonly take aggressive steps to limit the availability of exclusivity periods or to

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reduce their value. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction.

We may not be able to realize the expected benefits from our ongoing productivity initiatives.

In December 2007, we launched a new strategic initiative called "Forward" to enhance productivity by simplifying organizational structures throughout the Group, accelerating and decentralizing decision-making and redesigning the way we operate. Through this initiative, we aim to reduce our cost-base by approximately $1.6 billion by 2010 compared to 2007 levels. Our ability to achieve the expected cost savings, however, depends on a number of factors beyond our control. If we are unable to successfully complete "Forward" and other ongoing productivity initiatives, that could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to realize the expected benefits of our significant marketing efforts for our products.

The time between the launch of innovative "first-in-class" treatments and "me-too" or generic pharmaceuticals has shortened significantly in recent years. This trend is putting increasing pressure on our Pharmaceuticals Division to maximize revenue from each new product quickly following its launch, in order to recover the significant research and development costs and earn a return on that investment. A strong marketing message and rapid penetration of different geographic markets are vital for a product to attain peak sales as quickly as possible before the loss of patent protection or the entry of significant competitor products. As a consequence, we are required to invest significant resources in marketing and sales efforts. We continually evaluate the appropriateness of our marketing models, explore more efficient ways to support new product launches and adjust the composition of our sales force in response to changes in our product portfolio. For example, we announced a new commercial model for our US General Medicines business in 2008, aimed at driving sales growth while deploying resources more efficiently. If these or other efforts prove unsuccessful, this could have a material adverse effect on our business, financial condition and results of operations.

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

The demand for some products marketed by our Vaccines and Diagnostics Division, such as influenza vaccines, is seasonal, while the demand for other vaccines, such as pediatric combination vaccines, depends on changes in birth rates in developed countries. Some vaccines that make an important contribution to the division's net sales and profits, particularly the key seasonal influenza vaccine products, are considered commodities, meaning that there are few therapeutic differences among vaccines offered by competitors. In addition, the seasonal influenza vaccine products have suffered from price erosion due to growth in product supply across the industry. The ability to develop differentiated, effective and safe vaccines, to gain approval for inclusion in national immunization recommendation lists, and to consistently produce and deliver high-quality vaccines in time for the relevant disease seasons are critical to the success of our Vaccines and Diagnostics Division.

Our OTC Business Unit faces adverse impacts from questions of safety and efficacy, as well as more intense competition.

The OTC Business Unit of our Consumer Health Division sells over-the-counter medicines, many of which contain ingredients also sold by competitors in the OTC industry. In recent years, significant questions have arisen regarding the safety, efficacy and potential for misuse of certain products sold by our OTC Business Unit and its competitors. As a result, health authorities around the world have begun to re-evaluate some important over-the-counter products, leading to restrictions on the sale of some of them and even the banning of certain products. For example, in October 2008, acting in consultation with the FDA, we voluntarily re-labeled our US cough and cold medicines to indicate that these products

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should not be used in children under four years of age. Litigation has often followed actions such as these, particularly in the US. Additional actions and litigation regarding OTC products are possible in the future. In addition, particularly in the US, our branded OTC products compete against "store brand" products that are made with the same active ingredients but do not carry our trusted brand names, or the burden of expensive advertising. As a result, the store brands may be sold at lower prices. In recent years, consumers have increasingly begun to purchase store brand OTC products instead of branded products. These trends have had, and may continue to have, a significant adverse effect on the success of our OTC Business Unit. See also " The current economic and financial crisis may have a material adverse effect on our results" above.

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

The products we market, distribute and sell are either manufactured at our own dedicated manufacturing facilities or by third parties. In either case, we need to ensure that manufacturing processes comply with applicable regulations and manufacturing practices, as well as our own high quality standards. In particular, the manufacture of our products is heavily regulated by governmental authorities around the world, including the FDA. If we or our third party suppliers fail to comply fully with such regulations then there could be a government-enforced shutdown of production facilities or production lines, which in turn could lead to product shortages. A failure to comply fully with such regulations could also lead to a delay in the approval of new products. For example, in August 2008, our Sandoz Division's Wilson, North Carolina facility received a Warning Letter from the FDA which remains unresolved. The Warning Letter raises concerns regarding the Wilson facility's compliance with FDA Good Manufacturing Practice regulations, and states that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending NDAs, abbreviated NDAs or export certificate requests submitted by our Sandoz US affiliate. Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet highest quality standards. Voluntary recalls were made in September and in the fourth quarter of 2008 as part of the FDA review of the facility.

In addition, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may also rely on a single source of supply. As a result of these factors, the production of one or more of our products may be disrupted from time to time.

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

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

We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. We are required to make significant assumptions and estimates about future events in calculating the present value of expected future expense and liability related to these plans. These include assumptions about discount rates we apply to estimated future liabilities, expected returns on plan assets and rates of future compensation increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by the Group may differ materially from the actual results we experience due to changing market and economic conditions,

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higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the discount rate we apply in determining the present value of expected future obligations of one-half of one percent would have increased our year-end defined benefit obligation by $1.2 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see "Item 5. Operating and Financial Review and Prospects Item 5.A Operating Results Critical Accounting Policies and Estimates Retirement and other post-employment plans" and "Item 18. Financial Statements note 26". See also " The current economic and financial crisis may have a material adverse effect on our results" above.

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

Increasingly, significant portions of our sales, particularly in the US, are made to a relatively small number of US drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally, all of which are from the US, accounted for approximately 8%, 7% and 6%, respectively, of Group net sales from continuing operations in 2008. The highest amounts of trade receivables outstanding were for these three customers, and they amounted to 9%, 5% and 6%, respectively, of the Group's trade receivables at December 31, 2008. The trend has been toward further consolidation among our distributors, especially in the US. As a result, our distributors are gaining additional purchasing leverage, which increases the pricing pressures facing our businesses. Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantially greater than in the past. The increased purchasing power of these customers also increases the risk that we may not be able to effectively enforce the high standards that we expect of our distributors and customers. Each of these factors could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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We face intense competition for an increasingly limited pool of qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. As a result, we may be unable to attract and retain qualified individuals in sufficient numbers, which would have an adverse effect on our business, financial condition and results of operations.

Environmental liabilities may adversely impact our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on us to remediate contaminated sites. While we have set aside substantial provisions for worldwide environmental liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts for which we have provided in the Group consolidated financial statements. If we are required to further increase our provisions for environmental liabilities in the future, or if we fail to properly manage environmental risks, this could have a material adverse effect on our business, financial condition and results of operations. For more detail regarding environmental matters, see "Item 4.D Property, Plants and Equipment Environmental Matters" and "Item 18. Financial Statements note 19."

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 2008, 34% of our net sales from continuing operations were made in US dollars, 32% in euros, 7% in Japanese yen, 2% in Swiss francs and 25% in other currencies. During the same period, 31% of our expenses from continuing operations arose in US dollars, 28% in euros, 16% 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 sales, costs and earnings. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured in US dollars and the components of shareholders' equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5.A Operating Results Effects of Currency Fluctuations" and "Item 11. Quantitative and Qualitative Disclosures about Non-Product Related Market Risk."

We may be held responsible for potential misconduct of third-party agents, particularly in developing countries.

We have operations in approximately 140 countries around the world and are significantly expanding our activities in emerging growth markets. In many countries, particularly in less developed markets, we rely heavily on third-party distributors and other agents for the marketing and distribution of our products. Many of these third parties are small and do not have internal compliance resources comparable to those within our organization. Some of these countries are plagued by corruption. If our efforts to screen our third-party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties with applicable laws and regulations, which may have a negative effect on our reputation and our business.

Significant disruptions of information technology systems could adversely affect our business.

Our business is increasingly dependent on increasingly complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. Any significant breakdown or interruption of these systems, whether due to computer viruses or other causes, may result in the loss of key information and/or impairment of production and business processes, which could materially and adversely affect our business.

Earthquakes could adversely affect our business.

Our corporate headquarters, the headquarters of our Pharmaceuticals and Consumer Health Divisions, and certain of our major Pharmaceuticals Division production facilities are located near

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

Risks Related To Our ADSs

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

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

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

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

Item 4. Information on the Company

4.A History and Development of Novartis

Novartis AG

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

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

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The Novartis Group is a multinational group of companies specializing in the research, development, manufacturing and marketing of 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 "Item 18. Financial Statements note 32".

Important Corporate Developments 2006-2008

The following table provides an overview of certain important developments between 2006 and 2008:

2008

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

2007

April	Novartis announces a definitive agreement to divest Gerber to Nestlé for $5.5 billion, the final step in a divestment program to focus the Group's strategy on healthcare, with pharmaceuticals at the core.
July	Novartis completes the sale of its Medical Nutrition Business Unit to Nestlé for $2.5 billion, which had been announced in December 2006. Novartis enhances vaccines pipeline by gaining access to Intercell's key technologies and vaccines programs through an expanded strategic alliance. Novartis completes its fourth share repurchase program, initiated in August 2004. A total of 47,575,000 Novartis shares were repurchased for CHF 3 billion.
September	Novartis completes the sale of its Gerber Business Unit to Nestlé for $5.5 billion. Novartis and Bayer Schering Pharma AG (Bayer Schering) receive

regulatory approval to complete an agreement related to various rights for the multiple sclerosis treatment Betaseron®. Novartis received a one-time payment of approximately $200 million, principally for manufacturing facilities transferred to Bayer Schering, and received rights to market its own version of Betaseron® starting in 2009.

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October	Novartis Biologics is established as a focused unit to accelerate and optimize research and development of innovative biologic medicines, which make up 25% of the Novartis pre-clinical product pipeline.
November	Novartis completes its fifth share repurchase program, initiated in July 2007. A total of 63,173,000 Novartis shares were repurchased for CHF 4 billion.
December	Novartis announces a new strategic initiative called "Forward" to enhance productivity by simplifying organizational structures, accelerating and decentralizing decision-making and redesigning the way we operate. Through this initiative, we aim to reduce our cost base by approximately $1.6 billion by 2010 compared to 2007 levels. The initiative resulted in a restructuring charge of $444 million.

2006

February	Novartis completes the sale of its Nutrition & Santé business to ABN AMRO Capital France for $211 million. The transaction was announced in November 2005.
April	Novartis completes the acquisition of all remaining shares of Chiron Corporation that it did not already own for approximately $5.7 billion. A new division called Vaccines and Diagnostics is created to incorporate activities in human vaccines and molecular diagnostics, while the pharmaceutical activities of Chiron are integrated into the Pharmaceuticals Division.
September	Novartis acquires 100% of NeuTec Pharma plc, a UK biopharmaceuticals company specializing in hospital anti-infectives, for $606 million.
October	Novartis agrees to acquire the Japanese animal health business of Sankyo Lifetech Co., Ltd. The transaction closed in March 2007.
November	Novartis announces plans for a new strategic biomedical research and development center in Shanghai. This site will become an integral part of the Group's global research and development network.

For information on our principal expenditures on property, plants and equipment, see "Item 4. Information on the Company 4.D Property, plants & equipment." For information on our significant investments in research and development, see the relevant sections on research and development for each of our four operating divisions under "Item 4. Information on the Company 4.B Business Overview."

4.B Business Overview

OVERVIEW

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide with a broad portfolio that includes innovative medicines, preventive vaccines and diagnostic tools, generic pharmaceuticals and consumer health products. Novartis is the only company to achieve leadership positions in all of these areas. The Group's businesses are divided on a worldwide basis into the following four operating divisions:

Pharmaceuticals (brand-name patented pharmaceuticals)

Vaccines and Diagnostics (human vaccines and blood-testing diagnostics)

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Sandoz (generic pharmaceuticals)

Consumer Health (over-the-counter medicines, animal health medicines, and contact lenses and lens-care products)

Our strategy is to strengthen this healthcare portfolio through sustained investments in innovation, as well as through targeted acquisitions. In April 2008, we announced a significant agreement with Nestlé S.A. providing the right to acquire 77% majority ownership of Alcon Inc. (NYSE: ACL) in two steps and add this world leader in eye care to our portfolio. The potential value of these transactions is approximately $39 billion. In July 2008, the first step was completed when Novartis acquired a 25% stake in Alcon for $10.4 billion in cash. In the optional second step, we have the right to acquire Nestlé's remaining 52% majority stake between January 2010 and July 2011 for a fixed price of $181 per share, or approximately $28 billion. During this period, Nestlé has the right to require us to buy its remaining stake at a 20.5% premium to Alcon's share price at that time, but not exceeding $181 per share. We have no obligation to purchase the remaining 23% of shares held by Alcon minority shareholders at any time.

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

Novartis achieved net sales of $41.5 billion in 2008 from continuing healthcare operations, while net income amounted to $8.2 billion. We invested approximately $7.2 billion in research & development in 2008.

Headquartered in Basel, Switzerland, we employed approximately 96,700 full-time equivalent associates as of December 31, 2008, and have operations in approximately 140 countries around the world.

Pharmaceuticals Division

Our Pharmaceuticals Division researches, develops, manufactures, distributes, and sells branded pharmaceuticals in the following therapeutic areas: Cardiovascular and Metabolism; Oncology; Neuroscience and Ophthalmics; Respiratory; Immunology and Infectious Diseases; and Other. The Pharmaceuticals Division is organized into global business franchises responsible for the marketing of various products, as well as the Novartis Oncology business unit, responsible for the global development and marketing of oncology products. The Pharmaceuticals Division is the largest contributor of our divisions, accounting in 2008 for $26.3 billion, or 64%, of Group net sales from continuing operations, and for $7.6 billion, or 77%, of Group operating income from continuing operations (excluding Corporate income and expense, net).

Vaccines and Diagnostics Division

Our Vaccines and Diagnostics Division researches, develops, manufactures, distributes, and sells preventive vaccine treatments and diagnostic tools. It was formed in April 2006 following the acquisition of the remaining stake in Chiron Corporation not already held by Novartis. The division has two activities: Novartis Vaccines and Chiron. Novartis Vaccines is the world's fifth-largest vaccines manufacturer according to analyses of competitor annual reports. Key products include influenza, meningococcal, pediatric and travel vaccines. Chiron is a blood testing and molecular diagnostics activity dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world's blood supply. In 2008, the Vaccines and Diagnostics Division accounted for $1.8 billion, or 4%, of Group net sales from continuing operations, and provided $78 million, or 1%, of the Group's operating income from continuing operations (excluding Corporate income and expense, net).

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Sandoz Division

Our Sandoz Division is a leading global generic pharmaceuticals company that develops, manufactures, distributes, and sells drugs along with pharmaceutical and biotechnological active substances. Through Sandoz, Novartis is the only major pharmaceutical company to have leadership positions in both patented prescription drugs and generic pharmaceuticals. The Sandoz Division has activities in Retail Generics, Anti-Infectives and Biopharmaceuticals. In Retail Generics, we develop and manufacture active ingredients and finished dosage forms of pharmaceuticals no longer protected by patents, as well as supplying active ingredients to third parties. In Anti-Infectives, we develop and manufacture off-patent active pharmaceutical ingredients and intermediates mainly antibiotics for use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, we develop and manufacture protein- or biotechnology-based products no longer protected by patents (known as biosimilars or follow-on biologics) and provide biotech manufacturing to other companies on a contract basis. Sandoz offers some 950 compounds in more than 5,000 forms in 130 countries. Sandoz is the Group's second-largest division in terms of its contribution to the Group's net sales and operating income from continuing operations. In 2008, Sandoz accounted for $7.6 billion, or 18%, of Group net sales from continuing operations, and for $1.1 billion, or 11%, of Group operating income from continuing operations (excluding Corporate income and expense, net).

Consumer Health Division

Our Consumer Health Division consists of three business units: over-the-counter medicines (OTC), Animal Health and CIBA Vision. Each has its own research, development, manufacturing, distribution and selling capabilities. However, none are material enough to the Group to be separately disclosed as a segment. OTC offers over-the-counter self medications. Animal Health provides veterinary products for farm and companion animals. CIBA Vision markets contact lenses and lens care products. The Medical Nutrition and Gerber Business Units, which were previously included in the Consumer Health Division, were divested during 2007. The results of these business units have been reclassified and disclosed in this Form 20-F as discontinued operations in all applicable periods. The Medical Nutrition Business Unit offered health and medical nutrition products and Gerber offered food and other products and services designed to serve the needs of babies and infants. In 2008, the Consumer Health Division (excluding discontinued operations) accounted for $5.8 billion, or 14%, of Group net sales from continuing operations, and for $1 billion, or 11%, of Group operating income from continuing operations (excluding Corporate income and expense, net).

PHARMACEUTICALS

Overview

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

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

Cardiovascular and Metabolism

Oncology (including Hematology)

Neuroscience and Ophthalmics

Respiratory

Immunology and Infectious Diseases

Other

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The Pharmaceuticals Division is organized into global business franchises responsible for the marketing of various products as well as a business unit called Novartis Oncology responsible for the global development and marketing of oncology products. The Oncology Business Unit is not required to be separately disclosed as a segment in our consolidated financial statements since it shares common long-term economic perspectives, customers, research, development, production, distribution and regulatory environments with the remainder of the Pharmaceuticals Division. The Pharmaceuticals Division is the largest contributor among the four divisions of Novartis and reported consolidated net sales of $26.3 billion in 2008, which represented 64% of the Group's net sales from continuing operations.

The division is made up of approximately 80 affiliated companies which together employed 53,632 associates as of December 31, 2008, and sell products in approximately 140 countries. The product portfolio of the Pharmaceuticals Division includes more than 50 key marketed products, many of which are leaders in their respective therapeutic areas. In addition, the division's portfolio of development projects includes 152 potential new products, new indications or new formulations for existing products in various stages of clinical development.

Pharmaceuticals Division Products

The following table and summaries describe certain key marketed products and recently launched products in our Pharmaceuticals Division. We normally intend to sell all of our marketed products throughout the world. However, not all products and indications are currently available in every country. Compounds and new indications in development are, unless otherwise indicated, subject to required regulatory approvals and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. For some compounds, the development process is ahead in the US; for others, development in one or more other countries or regions is ahead of that in the US. Due to the uncertainties associated with the development process, and due to regulatory restrictions in some countries, it may not be possible to obtain regulatory approval for any or all of the new compounds and new indications referred to in this Form 20-F. In addition, for some of our products, we are required to conduct post-approval studies (Phase IV) to evaluate long-term effects or to gather information on the use of the product under special conditions. See " Regulation" for further information on the approval process. Certain of the products listed below have lost patent protection and are subject to generic competition. Others are subject to patent challenges by potential generic competitors. See below and " Intellectual Property" for further information on the patent status of our Pharmaceuticals Division's products.

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Key Marketed Products

Therapeutic area	Compound	Generic name	Indication	Formulation
Cardiovascular and Metabolism	*Diovan*	valsartan	Hypertension Heart failure Post-myocardial infarction	Capsule Tablet
	Diovan HCT/ Co-Diovan	valsartan and hydrochlorothiazide	Hypertension	Tablet
	Eucreas	vildagliptin and metformin	Type 2 diabetes	Tablet
	Exforge	valsartan and amlodipine besylate	Hypertension	Tablet
	Galvus	vildagliptin	Type 2 diabetes	Tablet
	Lescol/ Lescol XL	fluvastatin sodium	Hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia Secondary prevention of coronary events slowing the progression of atherosclerosis Heterozygous familial hypercholesterolemia in children and adolescents aged 9 years and older	Capsule Tablet
	Lotensin/ Cibacen	benazepril hydrochloride	Hypertension	Tablet
	Lotensin HCT/ Cibadrex	benazepril hydrochloride and hydrochlorothiazide	Hypertension Adjunct therapy in heart failure Progressive chronic renal insufficiency	Tablet
	Lotrel	amlodipine besylate and benazepril hydrochloride	Hypertension	Capsule
	Starlix	nateglinide	Type 2 diabetes	Tablet
	Tekturna/Rasilez	aliskiren	Hypertension	Tablet
	Tekturna HCT	aliskiren and hydrochlorothiazide	Hypertension	Tablet

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Therapeutic area	Compound	Generic name	Indication	Formulation
Oncology	*Exjade*	deferasirox	Chronic iron overload due to blood transfusions	Dispersible tablet for oral suspension
	Femara	letrozole tablets/letrozole	Advanced breast cancer in post-menopausal women (both as first- and second-line therapies) Early breast cancer in post-menopausal women following standard tamoxifen therapy (extended adjuvant therapy) Early breast cancer in postmenopausal women following surgery (upfront adjuvant therapy)	Tablet
	Gleevec/ Glivec	imatinib mesylate/imatinib	Certain forms of chronic myeloid leukemia Certain forms of gastrointestinal stromal tumor Certain forms of acute lymphoblastic leukemia Dermatofibrosarcoma protuberans Hypereosinophilic syndrome Aggressive systemic mastocytosis Myelodysplastic/myeloproliferative diseases	Tablet
	Proleukin	aldesleukin	Metastatic renal cell carcinoma Metastatic melanoma	Lyophilized powder for IV infusion upon reconstitution and dilution
	Sandostatin LAR & *Sandostatin SC*	octreotide acetate for injectable suspension & octreotide acetate	Acromegaly Symptoms associated with certain gastroenteropancreatic neuroendocrine tumors (carcinoid and VIPomas)	Vial Ampoule/pre-filled syringe
	Tasigna	nilotinib	Certain forms of chronic myeloid leukemia in patients resistant or intolerant to prior treatment including *Gleevec/Glivec*	Capsule
	Zometa	zoledronic acid for injection/zoledronic acid 4 mg	Prevention of skeletal-related events in patients with bone metastases from solid tumors Hypercalcemia of malignancy	Intravenous infusion

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Therapeutic area	Compound	Generic name	Indication	Formulation
Neuroscience and Ophthalmics	*Clozaril/ Leponex*	clozapine	Treatment-resistant schizophrenia Prevention and treatment of recurrent suicidal behavior in patients with schizophrenia and schizoaffective disorder	Tablet
	Comtan	entacapone	Parkinson's disease	Tablet
	Exelon & *Exelon* Patch	rivastigmine tartrate & rivastigmine transdermal system	Alzheimer's disease Dementia associated with Parkinson's disease	Capsule Oral solution Transdermal patch
	Focalin & *Focalin XR*	dexmethylphenidate HCl & dexmethylphenidate modified release	Attention deficit hyperactivity disorder	Tablet Capsule
	Ritalin & *Ritalin LA*	methylphenidate HCl & methylphenidate HCl modified release	Attention deficit hyperactivity disorder and narcolepsy Attention deficit hyperactivity disorder	Tablet Capsule
	Lucentis	ranibizumab	Wet age-related macular degeneration	Intravitreal injection
	Stalevo	carbidopa, levodopa and entacapone	Parkinson's disease	Tablet
	Tegretol	carbamazepine	Epilepsy Pain associated with trigeminal neuralgia Acute mania and bipolar affective disorders	Tablet Chewable tablet Oral suspension Suppository
	Trileptal	oxcarbazepine	Epilepsy	Tablet Oral suspension
	Visudyne	verteporfin	Wet age-related macular degeneration Pathological myopia Ocular histoplasmosis	Vial, intravenous infusion activated by non-thermal laser light
	Zaditor/ Zaditen	ketotifen	Allergic conjunctivitis	Eye drops
Respiratory	*Foradil*	formoterol		

		Asthma Chronic obstructive pulmonary disease	Aerolizer (capsules) Aerosol
Tobi	tobramycin	Pseudomonas aeruginosa infection in cystic fibrosis	Inhalation solution
Xolair	omalizumab	Allergic asthma	Lyophilized powder for reconstitution as subcutaneous injection

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Therapeutic area	Compound	Generic name	Indication	Formulation
Immunology and Infectious Diseases	*Certican*	everolimus	Prevention of organ rejection (heart and kidney)	Tablet Dispersible tablet for oral suspension
	Coartem/ Riamet	artemether and lumefantrine	Plasmodium falciparum malaria or mixed infections that include Plasmodium falciparum Standby emergency malaria treatment	Tablet
	Cubicin	daptomycin	Complicated skin and soft tissue infections (cSSTI) Right-sided endocarditis (RIE) due to Staphylococcus aureus Staphylococcus aureus bacteremia when associated with RIE or cSSTI	Powder for intravenous infusion
	Lamisil	terbinafine	Fungal infections of the skin and nails	Tablet Cream DermGel Solution Spray
	Myfortic	mycophenolic acid/mycophenolate sodium, USP	Prevention of graft rejection following kidney transplantation	Tablet
	Neoral	cyclosporine, USP Modified	Prevention of rejection following organ and bone marrow transplantation Non-transplantation autoimmune conditions such as severe psoriasis, nephrotic syndrome, severe rheumatoid arthritis, atopic dermatitis or endogenous uveitis	Capsule Oral solution
	Reclast/ Aclasta	*zoledronic acid/zoledronic acid 5 mg*	*Treatment of osteoporosis in postmenopausal women and to reduce risk of new clinical fractures after a recent low trauma hip fractures* *Treatment of osteoporosis in men*	*Intravenous infusion*

		Treatment of Paget's disease of the bone Reduction in Clinical fracture after recent low trauma hip fracture	
Simulect	basiliximab	Prevention of acute organ rejection in de novo renal transplantation	Vial for injection or infusion
Tyzeka/Sebivo	telbivudine	Chronic hepatitis B	Tablet

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Therapeutic area	Compound	Generic name	Indication	Formulation
	Voltaren/Cataflam	diclofenac sodium/potassium	Inflammatory forms of rheumatism Pain management	Tablet Capsule Drop Ampoule Suppository Gel Powder in sachet Transdermal patch
Other	*Combipatch/ Estalis/Estalis Sequi*	estradiol hemihydrate and norethisterone acetate	Treatment of symptoms of estrogen deficiency in postmenopausal women Prevention of osteoporosis in postmenopausal women	Transdermal patch
	Elidel	pimecrolimus cream	Atopic dermatitis (eczema)	Cream
	Estraderm TTS/ Estraderm MX	estradiol hemihydrate	Treatment of signs and symptoms of estrogen deficiency due to the menopause Prevention of accelerated postmenopausal bone loss	Transdermal patch
	Estragest TTS *Sequidot*	estradiol hemihydrate and norethisterone acetate	Treatment of symptoms of estrogen deficiency in postmenopausal women Prevention of postmenopausal osteoporosis	Transdermal patch
	Enablex/Emselex	darifenacin	Overactive bladder	Tablet
	Famvir	famciclovir	Acute herpes zoster including ophthalmic herpes zoster and decreased duration of post herpetic neuralgia Acute treatment of 1st episode and recurrent genital herpes infections, and for the suppression of recurrent genital herpes Treatment of recurrent herpes labialis (cold sores)	Tablet

		Indicated in immunocompromised patients with herpes zoster or herpes simplex infections	
Miacalcin/ Miacalcic	salmon calcitonin	Osteoporosis Bone pain associated with osteolysis and/or osteopenia Paget's disease Neurodystrophic disorders (synonymous with algodystrophy or Sudeck's disease) Hypercalcemia	Nasal spray Ampoule & multi-dose Vial for injection or infusion

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Therapeutic area	Compound	Generic name	Indication	Formulation
	Prexige	lumiracoxib	Osteoarthritis Acute pain Acute gout Primary dysmenorrhea	Tablet
	Vivelle Dot/ Estradot	estradiol hemihydrate	Estrogen replacement therapy for the treatment of the symptoms of menopause Prevention of postmenopausal osteoporosis	Transdermal patch
	Zelnorm/ Zelmac	tegaserod maleate/tegaserod	Irritable bowel syndrome with constipation Chronic idiopathic constipation	Tablet

Diovan (valsartan), together with *Diovan HCT/Co-Diovan* (valsartan and hydrochlorothiazide), is the world's No. 1 selling branded high blood pressure medicine (IMS data). *Diovan* is the only agent in its class approved to treat all of the following: high blood pressure (including children 6-16 years), high-risk heart attack survivors and patients with heart failure. First launched in 1996, *Diovan* is available in more than 100 countries for treating high blood pressure, in more than 90 countries for heart failure, and in more than 70 countries for heart attack survivors. In July 2008, the FDA approved *Diovan HCT* for the first-line treatment of hypertension in patients unlikely to achieve blood pressure control on a single agent. In November 2007, the FDA also granted *Diovan* an additional six months of marketing exclusivity beyond the valsartan patent expiration, until September 2012, following the completion of pediatric studies. *Diovan* and *Starlix* (nateglinide), an oral type 2 diabetes medication, are being evaluated for the prevention of new-onset type 2 diabetes and cardiovascular disease in patients with impaired glucose tolerance.

Gleevec/Glivec (imatinib mesylate tablets/imatinib) is a signal transduction inhibitor approved to treat certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). First launched in 2001, *Gleevec/Glivec* is available in more than 80 countries. *Gleevec/Glivec* is indicated for the treatment of newly diagnosed adult and pediatric patients with a form of CML. *Gleevec/Glivec* is approved in the US, EU and Japan to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL), a rapidly progressive form of leukemia; dermatofibrosarcoma protuberans, a rare solid tumor; hypereosinophilic syndrome and myelodysplastic/myeloproliferative diseases; and other rare blood disorders. In the US, *Gleevec/Glivec* is also approved for aggressive systemic mastocytosis. *Gleevec/Glivec* was submitted in the US, EU and Switzerland for adjuvant treatment in GIST. In December 2008, *Gleevec/Glivec* received approval in the US for this indication, and the dossier is currently under review in the EU and Switzerland, with approvals anticipated in the second quarter of 2009. The *Gleevec/Glivec* International Patient Assistance Program is now available in 80 countries and is currently providing access to *Gleevec/Glivec* for free to more than 20,000 patients worldwide through this innovative program.

Zometa (zoledronic acid for injection/zoledronic acid 4 mg) is a treatment for certain cancers that have spread to the bones. First approved in the US in 2001, *Zometa* is available in more than 80 countries. *Zometa* is approved for the treatment of patients with multiple myeloma and patients with documented bone metastasis from solid tumors, including prostate, breast

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and lung tumors. *Zometa* is also approved in most key markets for the treatment of hypercalcemia of malignancy (tumor-induced excessive levels of calcium). In December 2007, the FDA granted *Zometa* an additional six months of marketing exclusivity, until 2013, following the completion of a pediatric study in osteogenesis imperfecta. New clinical trial results (ABCSG-12 trial) showed that when *Zometa* is used as an adjuvant breast cancer treatment in premenopausal women, the drug reduced the risk of breast cancer returning. These results were resented at the 2008 American Society of Clinical Oncology meeting, and are being evaluated as part of a potential worldwide filing for a new indication for *Zometa*.

Femara (letrozole tablets/letrozole) is a once-daily oral aromatase inhibitor for the treatment of early stage or advanced breast cancer in postmenopausal women. *Femara* was first launched in 1996 and is currently available in more than 90 countries. *Femara* is approved in the US, EU and other countries as adjuvant therapy for postmenopausal women with hormone receptor-positive early breast cancer. *Femara* is also approved in the US, EU and other countries as extended adjuvant therapy for early breast cancer in postmenopausal women who are within three months of completing five years of adjuvant tamoxifen therapy. *Femara* is also approved in the US, EU and other countries as first-line treatment for postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer, and as treatment for advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy. In some countries, *Femara* is approved as neo-adjuvant (pre-operative) therapy for early stage breast cancer. In Japan, *Femara* is approved for the treatment of all hormone receptor-positive breast cancer in postmenopausal women. In 2008, *Femara* lost patent protection in several European markets, including Spain, which is expected to negatively impact growth. See " Intellectual Property" for further information.

Sandostatin SC/Sandostatin LAR (octreotide acetate/octreotide acetate for injectable suspension) is indicated for the treatment of patients with acromegaly, a chronic disease caused by over-secretion of pituitary growth hormone in adults. *Sandostatin* is also indicated for the treatment of certain symptoms associated with carcinoid tumors and other types of gastrointestinal neuroendocrine and pancreatic tumors. New clinical trial results presented in January 2009 at the Gastrointestinal Cancer Symposium of the American Society of Clinical Oncology showed *Sandostatin LAR* demonstrated antitumor benefit in patients with metastatic neuroendocrine tumors of the midgut. *Sandostatin* was first launched in 1988 and is approved in more than 85 countries. *Sandostatin SC* faces worldwide generic competition. However, patent protection continues in major markets for *Sandostatin LAR*. A new long-acting and monthly-administered competitor product, indicated for acromegaly, was launched in the US in late 2007. This competitor product may slow future growth of *Sandostatin LAR* in the US.

Neoral (cyclosporine, USP Modified) is an immunosuppressant to prevent organ rejection following a kidney, liver or heart transplant. This micro-emulsion formulation of cyclosporine is also indicated for treating selected autoimmune disorders such as psoriasis and rheumatoid arthritis. First launched in 1995, Neoral is marketed in approximately 100 countries. Despite our patent protection for *Neoral*, generic companies have launched competing products in the US, some European countries and elsewhere, and this competition is expected to continue. See " Intellectual Property" for further information.

Exelon (rivastigmine tartrate) capsules have been available since 1997 to treat mild to moderate Alzheimer's disease (AD) in more than 70 countries. In 2006 Exelon became the only cholinesterase inhibitor to be approved for mild to moderate Parkinson's disease dementia in addition to AD in both the US and EU. *Exelon* Patch (rivastigmine transdermal system) was approved in 2007 in the US and EU and is launched in over 40 countries. The once-daily *Exelon* Patch has shown comparable efficacy to the highest recommended doses of *Exelon* capsules, with significant improvement in cognition and overall functioning compared to placebo.

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Voltaren/Cataflam (diclofenac sodium/potassium) is a leading non-steroidal anti-inflammatory drug (NSAID) for the relief of symptoms in rheumatic diseases such as rheumatoid arthritis and osteoarthritis, and for various other inflammatory and pain conditions. *Voltaren/Cataflam* was first launched in 1973 and is available in nearly every country of the world. This product, which has been experiencing generic competition for many years (see " Intellectual Property" for further information), has a wide variety of dosage forms marketed by the Pharmaceuticals Division, including tablets, drops, suppositories, ampoules and topical therapy. In addition, in various countries, our Consumer Health Division's OTC Business Unit markets low-dose oral forms and the topical therapy of *Voltaren* as over-the-counter (OTC) products.

Lescol/Lescol XL (fluvastatin sodium) are lipid-lowering drugs used to reduce cholesterol. *Lescol/Lescol XL* are indicated as an adjunct to diet for the treatment of hypercholesterolemia and mixed dyslipidemia, and as an adjunct to diet to reduce cholesterol in adolescent boys and girls with heterozygous familial hypercholestrolemnia. In addition, for patients with coronary artery diseases, *Lescol/Lescol XL* are indicated for secondary prevention to reduce the risk of undergoing coronary revascularization procedures and to slow the progression of coronary atherosclerosis in patients with coronary heart disease. *Lescol was* first launched in 1994 and *Lescol XL* in 2000. Both are available in more than 90 countries.

Stalevo (carbidopa, levodopa and entacapone) is indicated for certain Parkinson's disease patients who experience end-of-dose motor (or movement) fluctuations, known as "wearing off". *Stalevo* was approved in the US in June 2003 and in the EU in October 2003, and is now approved in 79 countries. *Stalevo* is developed and manufactured by Orion Corporation, and is marketed by Novartis and Orion in their respective territories. Novartis has applied in the US and EU for approval to extend the indication for *Stalevo* to patients with early-stage Parkinson's disease. *Comtan* (entacapone) is also indicated for the treatment of Parkinson's disease patients who experience end-of-dose wearing off. *Comtan* is marketed in 31 countries under a licensing agreement with Orion.

Ritalin, Ritalin LA, Focalin, Focalin XR (methylphenidate HCl, methylphenidate HCl extended release, dexmethylphenidate HCl and dexmethylphenidate HCl extended release) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adults. *Ritalin* is also indicated for pediatric and adult narcolepsy. *Ritalin* was first marketed during the 1950's and is available in over 50 countries. *Ritalin LA* (long lasting) is available in 20 countries. *Focalin* comprises the active d-isomer of methylphenidate and therefore requires half the dose of Ritalin. *Focalin/Focalin XR* (extended release) are only available in the US, although *Focalin XR* has also been filed in Switzerland. A generic version of immediate-release *Focalin* was launched by competitors in the US in 2007.

Lotrel (amlodipine besylate and benazepril hydrochloride) is a high blood pressure treatment which is a single-pill combination of the angiotensin-converting enzyme (ACE) inhibitor benazepril, used in Lotensin/Cibacen, and the calcium channel blocker (CCB) amlodipine. Launched in 1995 and only available in the US, *Lotrel* received generic competition in May 2007, as a result of a "launch at risk" of a generic product by Teva Pharmaceuticals, despite a valid US patent until 2017. Our Sandoz Division has also launched an authorized generic version of this high blood pressure medicine. A trial date has not been set for the ongoing lawsuit against Teva, which risks potentially significant damages if Novartis prevails. There is also the possibility of an at-risk launch by other generic manufacturers after February 2009. Final results from the recently completed ACCOMPLISH trial suggest that a renin angiotensin aldosterone system (RAAS) blocker and amlodipine (calcium channel blocker) as a single-pill combination therapy initiated in high-risk hypertensive patients significantly

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reduces the risk of morbidity and mortality compared with a single-pill combination of ACE and diuretic.

Trileptal (oxcarbazepine) is an anti-epileptic drug for the treatment of partial seizures as adjunctive or monotherapy in both adults and children aged four years and above. In the US, *Trileptal* is approved for the treatment of epilepsy. *Trileptal* acts by stabilizing neuronal functions, thereby controlling and limiting the spread of seizures. It was first approved in Denmark in 1990, in the rest of the EU in 1999, and in the US in 2000. Today it is approved in 101 countries. Since 2007, *Trileptal* has been subject to generic competition, when generic versions of *Trileptal* were launched in the US and Europe. See " Intellectual Property" for further information.

Xolair (omalizumab) is the first humanized monoclonal antibody approved for the treatment of moderate to severe allergic asthma in the US and for severe allergic asthma in the EU in adolescents (aged 12 and above) and adults. It is approved in 61 countries including the US in 2003 and the EU in 2005. In 2007, a boxed warning was added to the US label with updated information on the risk and management of anaphylaxis. *Xolair* is being jointly developed with Genentech, Inc., and is co-promoted in the US by Novartis Pharmaceuticals Corporation and Genentech. We are developing *Xolair* to treat allergic asthma in children (ages 6 and older). In 2008 we also submitted a liquid formulation for European approval. In November 2008, we received a positive CHMP opinion for a liquid formulation of *Xolair* for European approval. In December 2008, *Xolair* was submitted for approval for use in children aged 6 to less than 12 years of age in the EU and US.

Famvir (famciclovir) is an antiviral agent for the treatment of acute herpes zoster (shingles), the treatment or suppression of recurrent genital herpes, and the treatment of recurrent herpes labialis (cold sores) in immunocompetent patients. In addition, *Famvir* is indicated for the treatment of recurrent mucocutaneous herpes simplex infections in HIV-infected patients. *Famvir* was first launched in 1994 and is registered in more than 70 countries. In the EU/EEA, *Famvir* is registered in 24 countries but marketed only in 17. There are also registered generics in ten EU countries. *Famvir* received generic competition in the US in September 2007. See " Intellectual Property" for further information.

Recently Launched Products

Lucentis (ranibizumab) is a recombinant humanized high affinity antibody fragment that binds to vascular endothelial growth factors. *Lucentis* is the first approved drug for wet age-related macular degeneration (AMD) that has been shown in Phase III studies to improve vision and vision-related quality of life. *Lucentis* was approved in the US in June 2006 and the EU in January 2007. It is now approved in more than 70 countries. *Lucentis* is developed in collaboration with Genentech, which holds the rights to market the product in the US. *Lucentis* is in Phase III development for the treatment of diabetic macular edema.

Exjade (deferasirox) is a breakthrough oral iron chelator that enables patients to be continuously protected from the life-threatening consequences of chronic iron overload. *Exjade* is the first once-daily oral iron chelator approved to remove excess iron caused by blood transfusions in patients who have a wide range of underlying anemias. Patients with congenital and acquired chronic anemias, such as thalassemia, sickle cell disease and myelodysplastic syndromes require transfusions as support for their anemia. *Exjade* was first approved in 2005 and is now approved in more than 90 countries including the US, EU and Japan. *Exjade* is being studied in non-transfusion dependent thalassemia and hereditary hemochromatosis.

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Exforge (valsartan and amlodipine besylate) is a single-pill combination of the angiotensin receptor blocker *Diovan* and the calcium channel blocker amlodipine. In 2007, the US and EU approved *Exforge* for the treatment of high blood pressure. It is now approved in over 70 countries and available in over 40. In July 2008, the FDA approved *Exforge* for the first-line treatment of hypertension in patients likely to need multiple drugs to achieve their blood pressure goals. Also in 2008 Novartis submitted a single pill combination of *Exforge* and Hydrochlorothiazide (HCT) for FDA approval.

Reclast/Aclasta (zoledronic acid 5 mg) is the first and only once-yearly infusion for the treatment of women with postmenopausal osteoporosis. *Reclast/Aclasta* is approved in almost 80 countries including the US, EU and Canada, and is the only osteoporosis treatment approved to reduce the incidence of fractures at all key fracture sites (hip, spine and non-spine) in the treatment of postmenopausal osteoporosis. It is also approved in more than 80 countries for the treatment of Paget's disease of the bone. The *Reclast/Aclasta* label was expanded in the EU and US to include the incidence of clinical fractures after low trauma hip fracture findings. The EU has also approved *Aclasta* for the treatment of osteoporosis in men, and *Reclast* is approved in the US as a treatment to increase bone mass in men with osteoporosis. *Reclast/Aclasta* has been submitted in the US and the EU for glucocorticoid-induced osteoporosis in men and women. Results of a trial investigating both the prevention and the treatment of glucocorticoid-induced osteoporosis demonstrated that *Reclast/Aclasta* significantly increased bone mineral density in the lumbar spine at 12 months compared to a comparator in both populations. *Reclast* is also under review for the prevention of osteoporosis in postmenopausal women in the US.

Tekturna/Rasilez (aliskiren) is the first and only approved direct renin inhibitor. Approved in the US and EU in 2007 for treating high blood pressure, it is now available in more than 65 countries. The product is known as *Tekturna* in the US and *Rasilez* in the rest of the world. We are investigating various *Tekturna/Rasilez* single-pill combination products. The first single-pill combination, *Tekturna/Rasilez* with hydrochlorothiazide called *Tekturna HCT* was approved by the US in January 2008 and in the EU in January 2009, where it is known as *Rasilez HCT*. In addition, we initiated the ASPIRE HIGHER clinical development program, the largest ongoing cardio-renal outcomes program worldwide, involving more than 35,000 patients in 14 trials. Data from the ALOFT (heart failure) and AVOID (kidney disease) studies, which are part of the ASPIRE HIGHER program, have been added to European product information. We also have additional single-pill combinations under development. A combination of *Tekturna/Rasilez* with *Diovan* (valsartan) has been submitted for approval in the US, and is in Phase III development in Europe. Also in Phase III development are *Tekturna/Rasilez* with the calcium channel blocker amlodipine and a triple-combination therapy with *Tekturna/Rasilez*, amlodipine and a diuretic.

Tasigna (nilotinib) is a signal transduction inhibitor of the tyrosine kinase activity of Bcr-Abl, Kit and the PDGF-receptor. Since 2007, *Tasigna* has gained regulatory approval in many major countries including the US, the EU and Switzerland, to treat a form of chronic myeloid leukemia (CML) in chronic and/or accelerated phase patients resistant or intolerant to existing treatment including *Gleevec/Glivec*. *Tasigna* is now approved in more than 50 countries including Japan, where it was approved in January 2009. A Phase III registration trial is in progress in newly diagnosed chronic phase CML (CML-CP). *Tasigna* is also being studied as a potential treatment for gastrointestinal stromal tumor (GIST), and the recruitment in the Phase III trial has been completed in GIST patients who have failed both *Gleevec/Glivec* and sunitinib. If the results of this study are positive, then we expect to make regulatory submissions for this indication in the second quarter of 2009.

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Galvus (vildagliptin) a new oral treatment for type 2 diabetes, and *Eucreas*, a single-pill combination of vildagliptin and metformin, have shown promising results during the rollout in Europe following approvals in early 2008. *Eucreas* was the first single-pill combination of a DPP-IV inhibitor to be launched in Europe. *Galvus* is approved in more than 50 countries and *Eucreas* is approved in more than 30 countries including the EU and Latin America. In the US *Galvus* received an "approvable letter" in February 2007 that included a request for additional clinical trial data. Some small clinical studies have started, however resubmission for US approval is not currently planned.

Extavia is an injectable therapy for multiple sclerosis (MS). It is a Novartis-branded version of interferon beta-1b, a product currently marketed by Bayer Healthcare Pharmaceuticals Inc. under the brand name Betaseron® in the US and by Bayer Schering Pharma under the brand name Betaferon® in the EU. Bayer Schering will supply the product to Novartis under a contract manufacturing arrangement. *Extavia* was approved in the EU in May 2008 and was launched in Germany and Denmark in January 2009. More European launches are planned in 2009. *Extavia* is filed for approval in the US. *Extavia* represents the first entry of Novartis into the treatment of MS.

Suspended or Withdrawn Products

Zelnorm/Zelmac (tegaserod maleate/tegaserod) is a partial serotonin-4 receptor agonist for the treatment of women between 18-54 years with irritable bowel syndrome with constipation, or chronic idiopathic constipation. It was first launched in 2001. Marketing and sales were suspended in the US in March 2007 based on a review of cardiovascular safety data. Subsequently, *Zelnorm/Zelmac* was withdrawn from the market, or had its sales suspended, in most of the countries where the product had been approved. However, it remains available in Brazil, Mexico, Ecuador, Honduras and the Dominican Republic. In 2008, we informed the FDA that there is no plan to resubmit a marketing application for *Zelnorm* in the US, and we closed a treatment Investigational New Drug program for the product. We have an emergency access program in the US and compassionate-use programs in Switzerland, Sweden, Denmark and Singapore to provide *Zelnorm/Zelmac* to specific patients.

Prexige (lumiracoxib) is an oral COX-2 inhibitor for osteoarthritis, acute pain, acute gout and primary dysmenorrhea. It was first approved in 2003 and had been approved in approximately 50 countries. Following a series of severe hepatic events reported in Australia and associated with the chronic use of 200 mg doses of *Prexige* or higher, health authorities, including Australia, the EU and Canada, took regulatory actions including withdrawal of licenses. In September 2007 the FDA sent Novartis a "not approvable" letter for the 100 mg once-daily dose in osteoarthritis. As of December 31, 2008, the only markets in which *Prexige* is still sold were Mexico, Dominican Republic, Ecuador and the Bahamas.

Compounds in Development

The following table and summaries describe certain key compounds and new indications for existing products currently in "Confirmatory" development within our Pharmaceuticals Division. Confirmatory refers to compounds that have established a clinical "proof-of-concept" (PoC) and are in the process of confirming safety and efficacy in patients. PoC clinical trials are small clinical trials (typically 5-15 patients) which combine elements of traditional Phase I/II testing. These customized trials are designed to give early insights into issues such as safety, efficacy and toxicity. The Confirmatory phase has components of traditional Phases II/III and includes the pivotal trials leading up to submission of a dossier to health

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authorities for approval. See " Research and Development" for further information. The traditional phases of development (I,II, and III) are defined as follows:

Phase I: First clinical trial of a new compound, generally performed in a small number of healthy 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.

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

Therapeutic area	**Project/ Compound**	**Generic name**	**Potential indication/ Disease area**	**Mechanism of action**	**Formulation/ Route of administration**	**Planned filing dates/ Current phase**
Cardiovascular and Metabolism	*Galvus*	vildagliptin	Type 2 diabetes	Dipeptidyl-peptidase 4(DPP-4) inhibitor	Oral	US (registration) EU (approved)
	Galvus fixed-dose combination (*Eucreas* in EU)	vildagliptin & metformin	Type 2 diabetes	Dipeptidyl-peptidase 4(DPP-4) inhibitor & insulin sensitizer	Oral	US (registration) EU (approved)
	Tekturna/ Rasilez fixed-dose combinations	aliskiren and hydrochlorothiazide	Hypertension	Direct renin inhibitor and diuretic	Oral	US (approved) EU (approved)
		aliskiren and valsartan		Direct renin inhibitor and angiotensin II receptor antagonist		US (registration) EU (2009/III)
		aliskiren and amlodipine		Direct renin inhibitor and calcium channel blocker		2009/III
		aliskiren, amlodipine and hydrochlorothiazide		Direct renin inhibitor, calcium channel blocker and diuretic		2010/III
	Diovan and *Starlix* (free combination)	valsartan and nateglinide	Prevention of new onset type 2 diabetes, cardiovascular morbidity and mortality (NAVIGATOR)	ARB and insulin secretagogue	Oral	2010/III
		aliskiren			Tablet	≥ 2012/III

Tekturna ALTITUDE		Renal and cardiovascular events in type 2 diabetes	Direct renin inhibitor		
LCI699	TBD	Heart failure	Aldosterone synthase inhibitor	Intravenous infusion	≥ 2012/II
LCZ696	TBD	Heart failure	ARB/NEP inhibitor	Oral	≥ 2012/II

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Therapeutic area	**Project/ Compound**	**Generic name**	**Potential indication/ Disease area**	**Mechanism of action**	**Formulation/ Route of administration**	**Planned filing dates/ Current phase**
Oncology	*Afinitor* (formerly RAD001)	everolimus	Advanced renal cell carcinoma	mTOR inhibitor	Tablet	US & EU (registration)
			Advanced secretory carcinoid tumors			2009/III
			Pancreatic Neuroendocrine tumors			2009/III
			Solid tumors			≥ 2012/II
	Tasigna	nilotinib	Gastrointestinal stromal tumor in patients having failed both *Gleevec/Glivec* and sunitinib	Signal transduction inhibitor	Capsule	2009/III
			Newly diagnosed chronic myeloid leukemia			2010/III
	EPO906	patupilone	Ovarian cancer	Microtubule stabilizer	Intravenous	2010/III
	SOM230	pasireotide	Cushing's disease	Somatostatin analogue	Subcutaneous injection	2010/III
			Refractory/ resistant carcinoid syndrome		Intramusculaar injection (monthly depot)	2010/II
			Acromegaly		Intramusculaar injection (monthly depot)	2011/III
	Zometa	zoledronic acid	Adjuvant breast cancer	Zoledronic acid	Intravenous	2010/III
	ASA404	TBD	Non-small cell lung cancer	Tumor vascular disrupting agent	Intravenous	2011/III
	PKC412	midostaurin	Acute myeloid leukemia	Multi-targeted kinase inhibitor (FLT-3 inhibition)	Oral	≥ 2012/III
			Aggressive systemic mastocytosis	Multi-targeted kinase inhibitor (c-kit inhibition)		2011/II
	LBH589	panobinostat	Cutaneous T-cell lymphoma	Deacetylase (DAC) inhibitor	Oral	2009/II

		Hodgkin's lymphoma		Oral	2010/II
		Hematological and solid tumors		Oral and Intravenous	≥ 2012/I
Exjade	deferasorix	Non-transfusion dependent iron overload in beta-thalassemia	Binds and removes iron	Dispersible tablet	≥ 2012/II
		Hereditary hemochromatosis			≥ 2012/II

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Therapeutic area	**Project/ Compound**	**Generic name**	**Potential indication/ Disease area**	**Mechanism of action**	**Formulation/ Route of administration**	**Planned filing dates/ Current phase**
Neuroscience and Ophthalmics	*Extavia*	interferon beta-1b	Multiple sclerosis	Interferon beta-1b immunomodulator	Injection	EU (approved) US (registration)
	AGO178	agomelatine	Major depressive disorder	MT1 and MT2 agonist and 5-HT2c antagonist	Oral	2009/III
	FTY720	fingolimod	Multiple sclerosis	Sphingosine-1-phosphate (S1P) receptor modulator	Oral	2009/III
	Lucentis	ranibizumab	Diabetic macular edema	Anti-VEGF monoclonal antibody fragment	Intravitreal injection	2010/III
	AFQ056	TBD	L-dopa induced dyskinesia in Parkinson's disease	mGluR5 antagonist	Oral	≥ 2012/II
	CAD106	TBD	Alzheimer's disease	Beta-amyloid-protein immunotherapy	Solution	≥ 2012/II
Respiratory	QAB149	indacaterol	Chronic obstructive pulmonary disease	Long-acting beta-2 agonist	Inhalation	US & EU (registration)
	Xolair	omalizumab	Allergic asthma in patients aged 6 to less than 12 years	Anti-IgE monoclonal antibody	Lyophilized powder for reconstitution as subcutaneous injection	US & EU (registration)
			Allergic asthma		Liquid formulation for subcutaneous injection	EU (registration) US (2009/III)
	MFF258	formoterol and mometasone furoate	Asthma	Long-acting beta-2 agonist and corticosteroid	Inhalation	2009/III
			Chronic obstructive pulmonary disease			2009/III
	TBM100	tobramycin	Pseudomonas aeruginosa infection in cystic fibrosis patients	Aminoglycoside antibiotic	Inhalation	2009/III
	Gleevec/Glivec	imatinib mesylate/ imatinib	Pulmonary arterial hypertension	Signal transduction inhibitor	Oral	2011/II
	NVA237	glycopyrronium bromide	Chronic obstructive pulmonary disease	Long-acting muscarinic antagonist	Inhalation	2011/II
	QVA149	indacaterol and glycopyrronium bromide	Chronic obstructive pulmonary disease	Long-acting beta-2 agonist and long-acting muscarinic antagonist	Inhalation	2011/II

NIC002	TBD	Smoking cessation	Nicotine Qbeta therapeutic vaccine	Injection	≥ 2012/II
QAX028	TBD	Chronic obstructive pulmonary disease	Long-acting muscarinic antagonist	Inhalation	≥ 2012/II
QMF149	indacaterol and mometasone furoate	Chronic obstructive pulmonary disease	Long-acting beta-2 agonist and corticosteroid	Inhalation	≥ 2012/II
		Asthma			≥ 2012/II

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Therapeutic area	Project/ Compound	Generic name	Potential indication/ Disease area	Mechanism of action	Formulation/ Route of administration	Planned filing dates/ Current phase
Immunology and Infectious Diseases	ACZ885	canakinumab	Cryopyrin-associated periodic syndrome (CAPS)	Anti IL-1b monoclonal antibody	Injection	US & EU (registration)
			Systemic onset juvenile idiopathic arthritis			2011/II
			Rheumatoid arthritis			≥ 2012/II
	Certican	everolimus	Prevention of organ rejection heart and kidney	Growth-factor-induced cell proliferation inhibitor	Oral	US (registration)
			Prevention of organ rejection liver			2010/III
	Reclast/ Aclasta	zoledronic acid 5 mg	Glucocorticoid-induced osteoporosis	Osteoclast mediated bone resorption inhibitor	Intravenous infusion	US & EU (registration)
			Post-menopausal osteoporosis prevention			US (registration)
	ABF656	albinterferon alfa-2b	Chronic hepatitis C	Interferon alpha-type activity	Injection	2009/III
	Elidel	pimecrolimus	Atopic dermatitis in infants	T-cell and mast cell inhibitor	Cream	2011/III
	SMC021	salmon calcitonin	Osteoarthritis	Regulator of calcium homeostasis	Oral	2011/III
			Osteoporosis	Inhibition of osteoclast activity		2011/III
	Mycograb	efungumab	Invasive candida	Antibody fragment vs. fungal HSP90	Intravenous infusion	≥ 2012/III
	SBR759	TBD	Hyperphosphatemia	Selective binding of phosphate (Fe(III) containing polymer)	Powder for oral suspension	2010/II
	PTZ601	TBD	Hospital bacterial infections	Carbapenem antibiotic	Intravenous infusion	2011/II
	AEB071	sotrastaurin	Prevention of organ rejection kidney	Protein kinase C inhibitor	Oral	≥ 2012/II
	AIN457	TBD	Psoriasis	Anti IL-17 monoclonal antibody	Lyophilisate in ampule	≥ 2012/II

Key Compounds in Development (select compounds in Phases II, III and Registration)

ABF656 (albinterferon alfa-2b) is a novel long-acting fusion protein having interferon alpha-type activity in Phase III development since 2006 for the treatment of chronic hepatitis C in combination with ribavirin. ABF656 was licensed from, and is being co-developed with, Human Genome Sciences Inc. We have co-promotion rights in the US and exclusive promotion and marketing rights in the rest of the world. In recent Phase III clinical trial results, based on an ITT analysis of the treatment group assigned to receive 900-mcg albinterferon alfa-2b every two weeks, albinterferon alfa-2b met its primary efficacy endpoint of non-inferiority to peginterferon alfa-2a. Additional Phase III results are expected in March 2009.

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ACZ885 is a human monoclonal antibody providing potent and selective blockade of interleukin-1b (IL-1b), a cytokine linked to inflammation, thus targeting IL-1b driven diseases. ACZ885 began Phase III development in 2007 for cryopyrin-associated periodic syndromes (CAPS), a group of rare disorders characterized by chronic recurrent urticaria, occasional arthritis, deafness, and other general signs of inflammation. A Phase I/II clinical study in CAPS patients showed immediate and long lasting clinical remission for patients treated with ACZ885. In December 2008, we filed ACZ885 for regulatory approval in this indication in the US, the EU and Switzerland. ACZ885 is also being developed for the treatment of systemic onset juvenile idiopathic arthritis and adult rheumatoid arthritis.

Afinitor (everolimus, formerly RAD001), a once-daily oral inhibitor of the mTOR pathway that has demonstrated broad clinical activity in multiple tumors, is in late stage development for the treatment of advanced renal cell carcinoma (RCC) and neuroendocrine tumors. *Afinitor* acts by directly inhibiting tumor cell growth and metabolism as well as the formation of new blood vessels (angiogenesis). Results from a Phase III study of *Afinitor* in metastatic RCC have been submitted to regulatory agencies in the US, EU and Switzerland. Additional submissions worldwide are planned. Additional Phase III studies are underway in patients with advanced secretory carcinoid tumors and pancreatic neuroendocrine tumors. Proof of concept with *Afinitor* as a single agent and in combination with other therapies has been demonstrated in the Phase I-II setting with tumor shrinkage or prolonged stable disease shown in lymphoma, breast and gastric cancers, hepatocellular carcinoma and in patients with tuberous sclerosis complex. Based on these data, Novartis plans to initiate new registration trials to evaluate the potential of *Afinitor* in these indications and in non-functional carcinoid tumors in combination with SOM230 in 2009. The active ingredient in *Afinitor* is everolimus, which is available in different dosage strengths under the trade name *Certican* for the prevention of organ rejection in heart and kidney transplant recipients. The trade name *Afinitor* is subject to regulatory approval.

AFQ056 is a metabotropic glutamate receptor 5 (mGluR5) antagonist with the potential to become the first approved treatment for Parkinson's disease levodopa-induced dyskinesia (PD-LID). No therapy has previously been approved for this disease, which is a complication after dopamine-replacement therapy in Parkinson's patients and which is characterized by a variety of hyperkinetic movements. AFQ056 recently showed positive results in a proof-of-concept trial in PD-LID and is proceeding in Phase II development.

AGO178 (agomelatine) is an MT1/MT2 receptor agonist and 5-HT2c antagonist for the treatment of major depressive disorder. AGO178 has a novel, synergistic mechanism of action which gives the potential for a more favorable adverse event profile compared with current therapies. Three Phase III trials are nearing completion in the US. Under license from Servier, we have the exclusive rights to develop and market the compound in the US and several other countries.

AIN457 is a monoclonal antibody neutralizing Interleukin-17A currently in Phase II development for the treatment of psoriasis and other immune mediated inflammatory diseases. Inhibition of IL-17A, a pro-inflammatory cytokine secreted by activated T-cells, represents a novel approach to treat a series of autoimmune and inflammatory diseases.

ASA404 is a unique Tumor Vascular Disrupting Agent (Tumor-VDA) that selectively causes disruption of established tumor vasculature, inhibition of tumor blood flow and extensive tumor necrosis. Phase II data in non-small cell lung cancer (NSCLC) show a significant survival benefit with ASA404 in combination with standard chemotherapy compared with chemotherapy alone. Phase III trials have now commenced enrollment with studies in first- and second-line NSCLC. Development of ASA404 for additional cancer indications is currently under evaluation. ASA404 was licensed from Antisoma plc, UK in April 2007.

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Certican (everolimus) is a growth-factor-induced cell proliferation inhibitor. In the US, *Certican* is currently in registration for the prevention of organ rejection in heart and kidney. In 2008, *Certican* entered Phase III development for the prevention of organ rejection in liver.

EPO906 (patupilone) is a novel microtubule stabilizer that has shown broad anti-cancer activity pre-clinically, including anti-vascular and anti-metastatic activity. Clinical activity of EPO906 as a single agent has been demonstrated in multiple solid tumors, including where taxanes are not traditionally active (e.g., CRC, brain metastases). The global development program for EPO 906 is based on a Phase III study which is underway in platinum resistant/refractory ovarian cancer.

FTY720 (fingolimod), a sphingosine-1-phosphate receptor modulator, has the potential to become the first oral disease-modifying treatment for patients with relapsing multiple sclerosis, a disabling neurological condition estimated to affect approximately 2.5 million people worldwide. Phase II data evidence a profound reduction in relapses and inflammatory disease activity as seen by magnetic resonance imaging, an effect that has since been maintained for three years. The Phase III program started in 2006, and is currently ongoing. First Phase III results from the TRANSFORMS study for FTY720 showed superior relapse-related efficacy at one year compared to interferon beta-1a. FTY720 was generally well-tolerated and its safety profile was in line with previous clinical experience. Further analysis of the TRANSFORMS data and results from two other ongoing Phase III studies will help to provide a more comprehensive assessment of FTY720's risk/benefit profile. FTY720 was licensed from Mitsubishi Tanabe Pharma Corporation.

LBH589 (panobinostat) is a novel, highly potent, multi-targeted pan-deacetylase inhibitor. The availability of both an oral and an intravenous (IV) formulation offers flexibility in developing combination regimens with multiple anticancer agents. In an ongoing Phase II study, LBH589 has shown activity in advanced refractory Cutaneous T-cell Lymphoma, a rare type of lymphoma that mainly affects the skin. In the Phase 1 setting, LBH589 demonstrated preliminary efficacy in patients with a range of diseases, including acute myeloid leukemia, Hodgkin's lymphoma, multiple myeloma, myelodysplastic syndrome and prostate cancer. A broad clinical program is ongoing to evaluate LBH589 as a single agent or in a combination regimen in Hodgkin's lymphoma, hematological malignancies and solid tumors. LBH589 is well tolerated in patients with advanced cancer when administered three times per week (oral) or weekly (IV).

LCZ696 is a novel dual-acting molecule that blocks the angiotensin receptor and inhibits the neutral endopeptidase (NEP) enzyme. The compound is set to enter Phase III development in 2009 in the treatment of heart failure, an indication in which ACE inhibitors are the current standard of care. Phase II studies involving 1,300 patients demonstrated that LCZ696 provides superior blood pressure lowering as compared to valsartan. LCZ696 was well tolerated.

MFF258 (formoterol and mometasone furoate) is in Phase III development, since 2006, for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. MFF258 combines the long-acting beta-2 agonist *Foradil* (formoterol fumarate) with mometasone in a metered dose inhaler device. We are co-developing this combination product with Schering-Plough.

Mycograb (efungumab) is an antibody fragment used in combination with antifungal agents for treatment of invasive candida infections. *Mycograb* was acquired as part of our acquisition of NeuTec Pharma in 2006. In 2007, the EU Committee for Medicinal Products for Human Use (CHMP) upheld its negative opinion from 2006 on the *Mycograb* submission by NeuTec, citing issues concerning the manufacturing process. We continue to work with European regulators to address these concerns.

PKC412 (midostaurin) is an oral, multi-targeted, kinase inhibitor that has shown activity in several neoplastic diseases, including acute myeloid leukemia (AML). PKC412 used in combination with standard chemotherapy (daunorubicin and high dose cytarabine) has improved clinical response rates of FLT3-mutated AML patients compared to chemotherapy alone (based on historical

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control). PKC412 as a single agent has also demonstrated clinical activity in mast cell leukemia patients and in patients with aggressive systemic mastocytosis (ASM). In 2008, a randomized Phase III study was initiated to evaluate the potential survival benefit in patients being treated with PKC412 in combination with chemotherapy compared to the use of chemotherapy alone in newly diagnosed patients with AML with FLT3 mutations. The trial is being conducted in collaboration with CALGB (Cancer and Leukemia Group B) and other cooperative groups. In addition, a phase II pivotal trial was initiated in 2008 to evaluate the activity of PKC412 as monotherapy in treating patients with ASM.

QAB149 (indacaterol) is a once-daily beta-2 agonist that offers sustained 24-hour bronchodilation with fast onset of action for the treatment of COPD. QAB149 is being developed in a single-dose dry-powder inhaler. Results from Phase III studies demonstrated a statistically significant improvement in lung function compared to placebo within five minutes of taking the first dose, and a favorable safety profile. QAB was submitted for regulatory approval in the US and EU in December 2008.

QMF149 is a once-daily fixed dose combination of the long-acting beta-2 agonist QAB149 and mometasone. It is being developed in Schering-Plough's 'Twisthaler' inhalation device for the treatment of asthma and COPD. QMF149 is jointly developed by Novartis and Schering-Plough, and is currently in Phase II development.

QVA149 is a once-daily fixed dose combination of the long-acting beta-2 agonist QAB149 and the long-acting muscarinic antagonist NVA237 (glycopyrronium bromide). QVA149 is in Phase II development (in a concept-1 dry-powder inhaler) for the treatment of COPD. The two bronchodilators were shown in free combination to provide greater bronchodilation and symptomatic control than either administered alone.

SOM230 (pasireotide) is a somatostatin analogue in development for Cushing's disease, acromegaly and carcinoid syndrome that is refractory/resistant to Sandostatin. Data from Phase II studies show significant hormone reductions in Cushing's disease and acromegaly patients, and achievement of partial or complete symptom control in patients with refractory/resistant carcinoid syndrome. Phase III studies are currently underway in Cushing's disease, acromegaly and carcinoid syndrome that is refractory/resistant to *Sandostatin*.

Terminated Projects

ACZ885 (canakinumab) for wet age-related macular degeneration

Aurograb for Staph. aureus infections

BCT194 for psoriasis

Lamisil (terbinafine) for onychomycosis

LBQ707 for solid tumors

LBY135 for solid tumors and hematological malignancies

Prexige (lumiracoxib) for osteoarthritis

TFP561 (tifacogin) for severe community acquired pneumonia

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 81%

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of 2008 net sales. The following table sets forth certain data relating to our principal markets in the Pharmaceuticals Division.

Pharmaceuticals	2008 Net sales to third parties ($ millions)	(%)
United States	8,616	33
Americas (except the United States)	2,346	9
Europe	10,138	38
Japan	2,615	10
Rest of the World	2,616	10
Total	**26,331**	**100**

Looking ahead we will selectively invest more in emerging growth markets such as China, Russia, South Korea and Turkey.

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 to ensure 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 three 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, and Changshu, China. 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 three biotechnology plants are in France, Switzerland and the US.

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.

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 or other 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.

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

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suppliers fail to comply fully with such regulations then there could be a product 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.

Marketing and Sales

The Pharmaceuticals Division serves customers with approximately 5,750 field force representatives in the US (including supervisors), and an additional 15,300 in the rest of the world. These trained representatives, where permitted by law, present the therapeutic and economic 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 healthcare 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 legally permitted as well as economically attractive.

We are seeing worldwide the increasing influence of customer groups beyond prescribers, such as payers, pharmacists and patients. Novartis is responding by increasingly using innovative pricing arrangements to accelerate and broaden market access, and we are developing programs to innovate our commercial model and tailor our marketing efforts to the distinct needs of these different stakeholder groups. As part of that effort, we announced in 2008 an innovative new program called "Customer Centric Initiative" to implement a new regional US business model that will better address customer needs and differences in local market dynamics. As part of this program, we have created five new regional units that have cross-functional responsibility for our full primary care product portfolio, replacing our nationally managed sales forces. This new model is designed to be more effective at driving sales growth by better meeting the diverse needs of multiple customers as well as a more efficient deployment of resources. We plan to reduce the size of our US sales force organization by about 550 full-time equivalent positions in a socially responsible manner, with more than half of the reductions planned from not filling already vacant positions.

Competition

The global pharmaceutical market is highly competitive and we compete against other major international corporations with substantial financial and other resources, which sell branded prescription pharmaceutical products. 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. Some generics manufacturers, however, are increasingly conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement and before final resolution of legal proceedings. In addition, we also face competition from over-the-counter (OTC) products that do not require a prescription from a physician.

There is finally 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.

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Research and Development

We are among the leaders in the pharmaceuticals industry in terms of research and development investment. In 2008, we invested approximately $5.7 billion in Pharmaceuticals Division research and development, which represented 21.7% of the division's total net sales. Our Pharmaceuticals Division invested $5.1 billion and $4.3 billion on research and development in 2007 and 2006 respectively. There are currently 152 projects in clinical development.

The discovery and development of a new drug is a lengthy process, usually requiring 10 to 15 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 a compound will not meet the requirements to progress further. In such an event, we may be required to abandon a compound in which we have made a substantial investment.

Research program

Our Research program is responsible for the discovery of new drugs. In 2003, we established the Novartis Institutes for BioMedical Research (NIBR). NIBR is headquartered in Cambridge, Massachusetts with more than 90,000 square meters of space housing more than 1,400 scientists and associates. Disease-area research groups in Cambridge include cardiovascular and metabolism disease, infectious disease, oncology, muscle disorders and ophthalmology. The Cambridge-based discovery research platforms include Developmental and Molecular Pathways, NIBR Biologics Center and Global Discovery Chemistry. An additional 2,300 scientists and technology experts conduct research in Switzerland, UK, Japan, Austria, China and two other US sites. Research is conducted in the areas of neuroscience, autoimmune disease, oncology, cardiovascular disease, dermatology, gastrointestinal disease and respiratory disease at these sites. In addition, research platforms such as the Center for Proteomic Chemistry are headquartered in the NIBR site in Basel, Switzerland. There were two changes to NIBR in 2008: first, the Biologics Center was transferred to the Novartis Pharmaceutical Division's Development organization; second, the Development organization transferred its exploratory development group to NIBR.

Our principal goal is to discover new medicines for diseases with high unmet medical need. To do so we focus our work in areas where we believe we have the potential to dramatically change the practice of medicine and sufficient information to make the target scientifically manageable. This requires the hiring and retention of the best talent, the focus upon fundamental disease mechanisms that are relevant across different disease areas, the continuous improvement in technologies for drug discovery and potential therapies, the close alliance with clinical colleagues, and the establishment of appropriate external complementary alliances.

All drug candidates are taken to the clinic via "proof-of-concept" trials to enable rapid testing of the fundamental efficacy of the drug while collecting basic information on pharmacokinetics, safety and tolerability, and adhering to the guidance for early clinical testing set forth by health authorities.

Over the past five years, the output from NIBR has grown progressively. The portfolio of pre-clinical and early clinical New Molecular Entities has increased over 50% in the last four years. Antibodies and protein therapeutics have grown to constitute 25% of NIBR's pre-clinical portfolio.

Development program

The focus of our Development program is to determine whether new drugs are safe and effective in humans. As previously described (see " Compounds in Development"), we view the development process as generally consisting of an "exploratory phase" where a "proof of concept" is established, and a "confirmatory phase" where this concept is confirmed in large numbers of patients. Within this paradigm, clinical trials of drug candidates generally proceed through the traditional three phases: I, II and III. In Phase I clinical trials, a drug is usually tested with about 20 to 80 normal, healthy volunteers. The tests

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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. people 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 assess the drug's safety and efficacy. The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug. See " Regulation."

Initiatives to optimize the research and development processes

At the end of 2007, Novartis launched Project Forward to enhance productivity and streamline decision making by eliminating unnecessary bureaucracy. Targeted initiatives within the Divisions will generate significant cost savings and realign resources to rapidly meet the needs of patients in a dynamically changing healthcare industry.

In the Pharmaceutical Division, as part of Project Forward, the Development organization is implementing Project Step Up, a program designed to strengthen and empower project teams, integrate decision making and cross-functional teams, and simplify governance, while maintaining functional excellence. Step Up also includes initiatives to enhance the partnership between Global Marketing and Development. We expect to implement Step Up by early 2009.

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. In particular, extensive controls exist on the non-clinical and clinical development of pharmaceutical products. These regulatory requirements, and the implementation of them by local health authorities around the globe, are a major factor in determining whether a substance can be developed into a marketable product, and the amount of time and expense associated with that development.

Health authorities, 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

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submission of an application to a regulatory authority does not guarantee that approval to market the product will be granted. Although the criteria for the registration of therapeutic drugs are similar in most countries, the formal structure of the necessary registration documents and the risk tolerance of the local health authorities 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 a product may finally be launched to the market.

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, manufacturing, labeling and approval for marketing of pharmaceutical products intended for commercialization in the US. The FDA continues to monitor the safety of pharmaceutical products after they have been approved for marketing in the US market. The pharmaceutical development and registration process is typically intensive, lengthy and rigorous. When a pharmaceutical company has gathered data which it believes sufficiently demonstrates a drug's 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. Throughout the life cycle of a product, the FDA also requires compliance with standards relating to good laboratory, clinical and manufacturing practices.

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

Once the FDA has approved an NDA 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.

European Union

In the EU, there are three main procedures for application for authorization to market pharmaceutical products in the EU Member States, the Centralized Procedure, the Mutual Recognition Procedure and the decentralized procedure. It is also possible to obtain a national authorization for

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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 for the European Community. The Centralized Procedure is mandatory for all biotechnology products and for new chemical entities in cancer, neurodegenerative disorders, diabetes and AIDS, and optional for other new chemical entities 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 CHMP) to provide the requested additional information. On day 210, the CHMP will then take a vote to recommend the approval or non-approval of the application. The final decision under this Centralized Procedure is an EU Community decision which is applicable to all Member States. This decision occurs on average 60 days after a positive CHMP recommendation.

Under the Mutual Recognition Procedure (MRP), the company first obtains a marketing authorization from a single EU member state, called the reference Member State. In the decentralized procedure the application is done simultaneously in selected or all Member States. 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 national marketing authorization 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 every five years.

Price Controls

In most of the markets where we operate, the prices of pharmaceutical products are subject to both direct and indirect price controls and to drug reimbursement programs with varying price control mechanisms. Due to increasing political pressure and governmental budget constraints, we expect these mechanisms to 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.

Direct efforts to control prices.

United States. In the US, as a result of the recent elections and the consolidating Democratic control of both houses of Congress and the Executive branch of government, there is a significant risk of legislative action to control prices including, potentially, amendments to the 2006 Medicare reform legislation which would enable the US government to use its significant purchasing power to demand additional discounts from pharmaceutical companies.

Europe. In Europe, our operations are subject to significant price and marketing regulations. Many governments are introducing healthcare reforms in a further attempt to curb increasing healthcare costs. In the EU, governments influence the price of pharmaceutical products through their control of national healthcare systems that fund a large part of the cost of such products to consumers. The downward pressure on healthcare costs in general in the EU,

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particularly with regard to prescription drugs, has become very intense. Increasingly high barriers are being erected against the entry of new products. In addition, prices for marketed products are referenced within Member States and across Member State borders, including new EU Member States.

Regulations favoring generics. In response to rising healthcare costs, many governments and private medical care providers, such as Health Maintenance Organizations, have instituted reimbursement schemes that favor the substitution of generic pharmaceuticals for more expensive brand-name pharmaceuticals. In the US, generic substitution statutes have been enacted by virtually all states and permit or require the dispensing pharmacist to substitute a less expensive generic drug instead of an original branded drug. Other countries have similar laws. We expect that the pressure for generic substitution will continue to increase.

Cross-Border Sales. Price controls in one country can also have an impact in other countries as a result of cross-border sales. In the EU, products which we have sold to customers in countries with stringent price controls can in some instances legally be re-sold to customers in other EU countries with less stringent price controls, at a lower price than the price at which the product is otherwise available in the importing country. In North America, products which we have sold to customers in Canada, which has relatively stringent price controls, are sometimes re-sold into the US, again at a lower price than the price at which the product is otherwise sold in the US. Such imports from Canada and other countries into the US are currently illegal. However, there are ongoing political efforts at the federal, state and local levels to change the legal status of such imports, and we expect those pressures to intensify as a result of the Democratic takeover of Congress and the White House.

We expect that pressures on pricing will continue worldwide, 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.

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 protection available under applicable law for significant product developments in all major markets. Among other things, patents may cover the products themselves, including the product's active ingredient and its formulation. Patents may cover processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents may also cover particular uses of a product, such as its use to treat a particular disease, or its dosage regimen.

The protection offered by such patents extends for varying periods depending on the grant, duration and enforceability of patents in the various countries. The protection afforded, which may vary from country to country, depends upon the type of patent and its scope of coverage. The duration of the protection will further depend on patent expiry data and the availability of patent term extensions, as well as other regulatory provisions for exclusivity such as data exclusivity, orphan drug status and pediatric exclusivity. We monitor our competitors worldwide and vigorously defend against infringements of our intellectual property.

However, patent protection for the active ingredients used in a number of our Pharmaceuticals Division's leading products has been challenged in on-going litigation or has expired, or is near expiry in the US and in other markets (for convenience the major EU countries and Japan are collectively referred to as "other markets"):

Diovan/Co-Diovan/Diovan HCT. We have patent protection (including extensions) on valsartan, the active ingredient used in our best-selling product *Diovan*, until 2011 in the major countries of

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the EU (until February 2011 in Spain, and until May 2011 in France, Germany, Italy and the UK); until September 2012 in the US, and until 2013 in Japan. No litigations concerning the *Diovan* patents are currently ongoing in the US.

Gleevec/Glivec. We have patent protection (including extensions) on imatinib, the active ingredient used in our leading product *Gleevec/Glivec*, until July 2015 in the US (including pediatric extension), until 2016 in the major EU countries, and until 2014 in Japan. Patent protection on a new crystal form of imatinib has been challenged in the US but no challenge has been made to the compound patent in the US. In Turkey, where Novartis does not have protection for the compound, we brought suit in 2007 for infringement of the imatinib formulation, indication and crystal form patents against a local company that had obtained generic marketing authorization for a generic version of *Glivec*. We obtained a preliminary injunction, but it was lifted in 2008. That litigation is ongoing. In Russia, we have a patent covering the compound and a permanent injunction was obtained against a company that filed for marketing authorization for a generic version of *Glivec*. An appeal of the lower court's ruling is pending.

Zometa and *Reclast/Aclasta* Patent protection on zoledronic acid, the active ingredient in these products, will expire in 2013 in the US and 2012 in other major markets. Patent litigation against a generic manufacturer who has challenged the patent is on-going. An at-risk launch of a generic version of *Zometa* is possible in the US beginning at the end of 2010 when the 30-month stay period expires, absent any negative court decision before then. For *Reclast,* the 30-month stay period expires in May 2011, making an at-risk launch possible at that time, or earlier in the event of an earlier negative court decision.

Femara. Patent protection for the active ingredient in *Femara* will expire in 2011 in the US as well as in major European markets, and in 2012 in Japan. Patent litigation against a generic manufacturer who challenged this patent has been settled.

Sandostatin. Patent protection for the active ingredient of *Sandostatin* has expired. Generic versions of *Sandostatin SC* have been approved in the US and elsewhere. Patents protecting the *Sandostatin LAR* formulation, the long-acting version of *Sandostatin* which represents a majority of our sales, expire in 2014 and beyond in the US and in 2010 in other markets outside the US.

Neoral. Patent protection for the cyclosporin ingredient of *Neoral* has expired worldwide. Patent protection covering the *Neoral* micro-emulsion formulation patent and other patents is due to expire in September 2009 and beyond in major markets. However, generic cyclosporin products competing with *Neoral* have already entered the market in the US, Germany, Japan, Canada and elsewhere. A permanent injunction has been obtained in the Netherlands and preliminary injunctions have been obtained in Spain and the UK against certain manufacturers. Injunctions have so far not been obtained in other countries. Revenue from this product has declined from its peak, and may decline significantly in the future as a result of ongoing generic competition.

Lucentis. Patent protection for the active ingredient in *Lucentis* expires in 2018-22 in Europe, Japan and other major markets. In the US *Lucentis* is marketed by Genentech. In countries other than the US, Genentech has licensed *Lucentis* to Novartis.

Exelon. Patent protection for the active ingredient in *Exelon*, granted to Proterra and licensed to Novartis, is expiring 2012 in the US and 2011 in most other markets. Novartis holds a patent on a specific isomeric form of the active ingredient used in *Exelon* which expires in 2012-14 in major markets. Generic manufacturers filed applications to market a version of *Exelon* capsules in the US, but not the *Exelon* Patch, and challenged our patents. The resultant US lawsuits have been settled. Under the terms of the settlement agreements, Novartis has granted the generic manufacturers a license to our US patents covering *Exelon.* The agreements generally permit the generic manufacturers to launch a generic version of *Exelon* capsules, but not of the *Exelon* Patch, prior to the patent expiration date. A generic manufacturer of Exelon capsules has

filed a lawsuit

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challenging a Canadian patent on the specific isomeric form of the active ingredient which expires September 2009. The lawsuit is ongoing.

Voltaren. Patent protection for the active ingredient in *Voltaren* has expired. Revenue from this product may decline significantly in the future as a result of ongoing generic competition.

Lescol. Patent protection for the active ingredient in *Lescol* will expire in 2012 (including pediatric exclusivity) in the US and has already expired in August 2008 in major European markets. Formulation patents expire 2012 and beyond. Patent litigation under the compound patent is ongoing against a generic manufacturer who filed for marketing authorization for a generic version of *Lescol* in the US, challenging the patent on the active ingredient and one formulation patent. An at-risk launch of a generic version of this product is possible in the US beginning in February 2011, at the expiration of the 30-month stay, absent any negative court decision before then. Other generic manufacturers have filed for marketing authorization challenging formulation patents for *Lescol XL* in the US. In Europe, several generic manufacturers have challenged the validity of formulation patents for *Lescol XL* that expire in 2017 at the European Patent Office (EPO), and in court in a number of countries. Conflicting decisions by the EPO, the UK and the Netherlands with the EPO upholding the patent, the courts revoking it are now on or subject to appeal.

Exjade. Patent protection for the active ingredient in *Exjade* will expire in 2019 in the US and 2021 in other markets.

Comtan. Patent protection for entacapone, the active ingredient in *Comtan,* which we licensed from Orion, will expire in the US in 2013 and in Europe in 2012. Other patents, such as a polymorph patent, are also granted. Patent litigation concerning the patent on entacapone by Orion is ongoing against generic manufacturers who have challenged these patents in the US. An at-risk launch of a generic version of this product is possible in the US beginning in February 2010, at the expiration of the 30-month stay, absent any negative court decision before then. Novartis is not party to the pending litigation.

Stalevo. One of the active ingredients in the combination product *Stalevo* is entacapone, the active ingredient in *Comtan.* Patent protection for entacapone will expire in 2012-13 (see above). *Stalevo* is protected by additional patents expiring up to 2020. Patent litigation, by Orion, is ongoing against generic manufacturers who have challenged the patent on entacapone and formulation patents in the US. An at-risk launch of a generic version of this product is possible in the US beginning in June 2010, at the expiration of the 30-month stay, absent any negative court decision before then. Novartis is not party to the pending litigation.

Ritalin LA. Patent protection for the active ingredient of *Ritalin LA* has expired. The formulation of *Ritalin LA* and its use is covered by patents granted to Celgene and Elan and licensed to Novartis, expiring up to 2018 in the US. Patent litigation against generic manufacturers who challenged these patents is ongoing in the US. An at-risk launch of a generic version of this product in the US is possible beginning in April 2009, at the expiration of the 30-month stay, absent any negative court decision before then.

Focalin. The formulation of *Focalin XR* and its use are covered by patents granted to Celgene and Elan and licensed to Novartis. Protection expires 2015-18 in the US and in other markets. Patent litigation against generic manufacturers who challenged these patents is ongoing in the US. An at-risk launch of a generic version of this product is possible in the US beginning in February 2010, at the expiration of the 30-month stay, absent any negative court decision before then.

Exforge. is a single-pill combination medication of amlodipine besylate and valsartan. The valsartan patent expires 2011-13 (see above). The *Exforge* pill patent will expire in 2019 and has been challenged in both the US and Europe. In Europe opposition proceedings are ongoing.

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Lotrel is protected by a patent on compositions containing amlodipine and benazepril in the US until 2017. Patent litigation challenging the patent is ongoing in the US. A trial is expected in 2010. Low-dose generic versions of *Lotrel* have been launched at-risk by one generics manufacturer. It is possible that other generics manufacturers will launch their own generic versions of *Lotrel* at risk at some time after February 2009 when the FDA can fully approve such other generic versions. Revenue from this product has declined significantly, and may decline further in the future as a result of continued and additional generic competition.

Trileptal. Patent protection for the active ingredient of *Trileptal* has expired. A patent has been granted in the US directed to a method of treating seizures with our marketed formulations of *Trileptal,* expiring 2018. In Europe, the corresponding granted patent is currently being challenged. Patent litigation was started against generic manufacturers that have filed applications to market generic versions of *Trileptal* in the US and challenge the validity of *Trileptal* patents, and has now been withdrawn. Generic versions of *Trileptal* have been marketed in the US and elsewhere. Revenue from this product has declined, and may decline significantly in the future as a result of ongoing generic competition.

Xolair. Patent protection for the active ingredient in *Xolair* will expire in 2018 in the US and in 2017 in other markets.

Famvir. Patent protection for the active ingredient in *Famvir* expires in 2010 in the US, and has expired in most other markets. Patents on methods of use will expire in 2014 and 2015. Patent litigation against the generic manufacturers which challenged these patents is ongoing in the US. In 2007, one generic manufacturer launched generic *Famvir* at-risk in the US, and related litigation is ongoing. Revenue from this product has declined, and may decline significantly in the future as a result of ongoing generic competition.

Tekturna/Rasilez. Patent protection for the active ingredient of *Tekturna/Rasilez* will expire in 2018 in the US and between 2015 and 2020 in other markets.

Tasigna. Patent protection for the active ingredient in *Tasigna* will expire in 2023 in the US and other major markets.

Galvus. Patent protection for the active ingredient of *Galvus* is estimated to expire, with extensions in 2024 in the US and 2019-24 in other markets.

Zelmac/Zelnorm. Patent protection for the active ingredient of *Zelmac/Zelnorm* will expire in 2016 in the US and 2012 in Europe and other markets.

Prexige. Patent protection for the active ingredient in *Prexige* will expire in 2018 in the US and major countries.

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

VACCINES AND DIAGNOSTICS

Our Vaccines and Diagnostics Division is a leader in the research, development, manufacturing and marketing of vaccines and blood tests and instruments worldwide. As of December 31, 2008, the Vaccines and Diagnostics Division employed 4,774 associates worldwide in 16

countries. In 2008, the Vaccines and Diagnostics Division had consolidated net sales of $1.8 billion representing 4% of total Group net sales from continuing operations.

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The Novartis Vaccines and Diagnostics Division is the world's fifth-largest vaccines manufacturer, according to analyses of competitor annual reports, and is growing at double-digit rates. Our vaccine products include influenza, meningococcal, pediatric, adult and travel vaccines. Our blood testing business is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools.

The current product portfolio of our Vaccines and Diagnostics Division includes more than 20 marketed products, many of which are their respective market leaders. In addition, the division's portfolio of development projects includes nine potential new products and new indications or formulations for existing products in various stages of clinical development.

Menveo (MenACWY-CRM), a quadrivalent conjugate vaccine for the prevention of the A, C, Y and W-135 strains of meningococcal disease, was submitted for marketing authorization in the US and Europe in 2008 for use in individuals 11-55 years old. Our *Menveo* Phase III program for the additional indication of the prevention of the disease in persons aged 2 months to 10 years old is ongoing, and it is expected to be expanded by 1,500 additional infants following recent discussions with the FDA. As a result of this new requirement, the US submission of *Menveo* for use in infants is not expected until 2011.

The menB vaccine has shown potential to be the first to protect infants as young as six months from the deadly meningococcal B serogroup. Clinical trial results issued in 2008 showed nearly all infants age six to 12 months in a Phase II study generated a protective immune response as early as one month after the second dose against strains representing multiple antigens in the vaccine. Another 2008 study showed the vaccine worked in infants who received it starting at two months of age. A Phase III trial in infants and children is underway.

Ixiaro vaccine for the prevention of Japanese encephalitis in travelers to Asia has been submitted for marketing approval in the US and in the EU, where it received a positive opinion from the CHMP in December 2008. Further pediatric studies with the vaccine are planned.

Novartis has continued to strengthen its vaccine pipeline through a number of new partnerships in 2008. We received an exclusive license to AlphaVax' investigational cytomegalovirus vaccine for prevention of disease in newborns. The vaccine is completing Phase I development. Intercell also transferred on an exclusive basis its preclinical Group B streptococcus (GBS) vaccine program to Novartis. The GBS vaccine program was part of the vaccine portfolio for which Intercell had granted license options to Novartis under a strategic partnership entered into in 2007.

In 2008, the Vaccines and Diagnostics Division continued efforts towards full-scale seasonal influenza vaccine production and recognized the sale of our H5N1 pre-pandemic vaccine to the US government. Separately, the division withdrew its application for an EU centralized marketing authorization application (MAA) for *Aflunov,* another pre-pandemic vaccine, when the request by the EMEA for additional data, as required by the pre-pandemic guideline, could not be met within the applicable regulatory timeframe. Further clinical trials are currently underway after which the MAA will be re-submitted.

The division also expanded its line of nucleic acid testing products in Europe in 2008 and rolled-out new tests for the West Nile Virus. The diagnostics product *Ultrio* assay 3/3 was approved in August 2008.

Our diagnostics collaboration continues with Gen-Probe Inc. This arrangement relates to the development and commercialization of nucleic acid testing products under the *Procleix* brand name to screen donated blood, plasma, organs and tissue for viral infection.

Our Vaccines and Diagnostics Division is continuing to lead efforts on the corporate diversification strategy of Novartis AG. The Novartis Vaccines Research Center of Excellence in Virology was opened in Cambridge, MA in September 2008 as an important step towards identifying vaccines to prevent Respiratory syncytial virus, HIV and Influenza.

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In January 2009, the US Department of Health and Human Services had awarded Novartis Vaccines and Diagnostics a contract for up to $486 million over eight years to support the design, construction, validation and licensing of the division's cell culture-based manufacturing facility at Holly Springs, North Carolina, to provide a pre-pandemic supply of influenza vaccine, and to provide the capacity to manufacture 150 million doses of pandemic vaccine within six months of declaration of an influenza pandemic.

Vaccines and Diagnostics Division Products

The summary and the tables that follow describe key marketed products and potential products in development in our Vaccines and Diagnostics Division. Subject to required regulatory approvals and, in certain instances, contractual limitations, we intend to sell our marketed products throughout the world. However, not all products are available in every country. Regarding our products in development, these products and indications are in various stages of development throughout the world. For some products, the development process is ahead in the US; for others, development in one or more other countries or regions is ahead of that in the US. Due to the uncertainties associated with the development process, and due to regulatory restrictions in some countries, it may not be possible to obtain regulatory approval for any or all of the new products referred to in this Form 20-F. See " Regulation" for further information on the approval process.

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Key Marketed Vaccine Products

Product	Indication
Influenza Vaccines	
Agrippal	A purified surface antigen influenza vaccine for adults and children above six months of age
Begrivac	A preservative free influenza vaccine for adults and children above six months of age
Fluad	A purified surface antigen influenza vaccine containing the proprietary MF59 adjuvant for the elderly
Fluvirin	A purified surface antigen influenza vaccine for adults and children above four years of age
Optaflu	Cell culture-based influenza vaccine for adults above 18 years of age
Meningococcal Vaccines	
Menjugate	Meningococcal C vaccine for children above 2 months of age
Travel Vaccines	
Encepur Children *Encepur* Adults	Tick-borne encephalitis vaccine for children 1-11 years of age and for adults 12+ years of age
Rabipur/Rabavert	Vaccine for rabies, which can be used before or after exposure (typically animal bites)
Pediatric Vaccines	
Quinvaxem	Fully-liquid pentavalent vaccine combining antigens for protection against five childhood diseases: diphtheria, tetanus, pertussis (whooping cough), hepatitis B and Haemophilus influenzae type b for children above 6 weeks of age
Polioral	Live, attenuated, oral poliomyelitis vaccine (Sabin) containing attenuated poliomyelitis virus types 1, 2 and 3 from birth

Other Marketed Vaccine Products

The Vaccines and Diagnostics Division also markets additional products in travel vaccines (*e.g., Typhoral* L, *Havpur*), pediatric vaccines (*e.g.,* IPV-*Virelon*, TD-*Virelon*, *Diftetall*, *Vaxem-Hib*) and adult vaccines (*e.g., Tetanol*, Td-*Virelon*).

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Vaccine Products in Development

Therapeutic Area	Project/Compound	Potential Indication/Disease Area	Planned filing dates/ Current phase
Influenza	*Optaflu*	Cell culture-based trivalent seasonal influenza vaccine	EU registered; US 2009/Phase III
	Agrippal	Egg-based trivalent seasonal influenza vaccine	EU registered; US Filed
	Fluad pediatric	A purified surface antigen influenza vaccine containing the proprietary MF59 adjuvant in development for children 6-36 months of age	Phase II
	Focetria	H5N1 influenza vaccine to be used in a pandemic. Approved in the EU, but an update to the file will be required at the time of a pandemic	EU approved in May 2007; annual update pending a pandemic
	Aflunov	H5N1 influenza vaccine to be used before a pandemic occurs	EU submitted; US Phase II
Meningitis	*Menveo*	Quadrivalent meningitis vaccine for strains A, C, Y and W-135 for infants, adolescents and adults	Submitted (adolescents & adults) (US & EU) 2011/Phase III (infants)
	MenB		2009/Phase III
P aeruginosa		Prophylactic vaccine for P aeruginosa infections[1]	Phase II
JEV[1]	*Ixiaro*	Prophylactic vaccine against Japanese encephalitis virus (JEV)	Submitted (US & EU)
HCV[1]		Therapeutic Hepatitis C virus (HCV) vaccine	Phase I
		Prophylactic HCV vaccine	Phase I
HIV[1]		Prophylactic HIV vaccine	Phase I
GBS		Prophylactic Group B Streptococcus (GBS) vaccine	Phase I
H pylori		Prophylactic vaccine for H pylori	Phase I
CMV[2]		Prophylactic vaccine for cytomegalovirus	Phase I

(1) In collaboration with Intercell

(2) In collaboration with AlphaVax

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Key Marketed Diagnostics Products

Therapeutic Area	Project/Compound	Potential Indication/Disease Area	Status
Blood Testing	*Procleix* eSAS System	Semi automated modular instrument solution supporting Duplex and *Ultrio* NAT assays	EU approved (CE marked) US approved
	Procleix TIGRIS System	Fully automated instrument solution supporting *Ultrio* NAT assays	EU approved (CE marked) US approved (FDA BLA approval for TESTs supported)
	Procleix Duplex Assay	NAT assay designed to detect HIV-1, HCV through a single test	US approved EU approved (CE marked)
	Procleix WNV Assay	First NAT assay approved by the FDA to detect West Nile virus.	US approved EU approved (CE marked)
	Procleix Ultrio Assay	NAT assay designed to detect HIV-1, HCV and HBV through single testing process	EU approved (CE marked) for use on *eSAS* and *Tigris* US approved for use on *eSAS* and *Tigris*

Diagnostic Products in Development

Therapeutic Area	Project/Compound	Potential Indication/Disease Area	Planned filing dates/ Current phase
Blood Testing	*Procleix Ultrio* + Assay	NAT assay designed to detect HIV-1, HCV and HBV through single testing process with a higher sensitive to HBV	2009 (for use on *eSAS* and *Tigris*)/ Phase III
	Parvo test	NAT test designed to detect the Parvo B19 virus	Discovery
	Dengue test	NAT test designed to detect the Dengue virus	Discovery
Clinical Diagnostics	*Mis-folded protein assay*	Novel technology to detect abnormal protein particles that cause several neurodegenerative diseases such as Diabetes, Alzheimer's, Parkinson's in patients	Discovery
Molecular Diagnostics	*Novachip*	Multi-analyte detection proprietary platform which enables the diagnostics of complex diseases by providing multi-parameter array technology and multiple-analyte applications	Pre-clinical
	CRM	Markers for diagnostic and early detection of allograft rejection and dysfunction based on gene expression profiling	Pre-clinical
	ACZ	Molecular test that can predict Rheumatoid Arthritis	Pre-clinical

patients' response to Novartis' ACZ885

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Principal Markets

The principal markets for our Vaccines and Diagnostics Division include the US and Europe. The following table sets forth the aggregate 2008 net sales of the Vaccines and Diagnostics Division by region:

Vaccines and Diagnostics	2008 Net sales to third parties	
	($ millions)	(%)
United States	765	43
Americas (except the United States)	30	2
Europe	683	39
Rest of the World	281	16
Total	**1,759**	**100**

Sales of certain vaccines, including influenza and tick borne encephalitis vaccines, are subject to seasonal variation. Sales of the majority of our other products are not subject to material changes in seasonal demand.

Research and Development

In 2008, the Vaccines and Diagnostics Division invested $360 million in research and development, which amounted to 20.5% of the division's net sales. The Vaccines and Diagnostics Division invested $295 million and $148 million on research and development in 2007 and 2006, respectively.

While research and development costs for vaccines traditionally have not been as high as for pharmaceuticals, a robust clinical program including Phase I to Phase III must be performed by the manufacturer to obtain a license for commercialization. See " Pharmaceuticals Compounds in Development" and " Pharmaceuticals Research and Development." 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.

Production

We manufacture our vaccines products at four facilities in Europe and Asia. Our principal production facilities are located in Liverpool, UK; Marburg, Germany; Siena and Rosia, Italy; and Ankleshwar, India. We continue to invest and upgrade these sites to ensure that previously initiated remediation efforts are completed and meet quality standards. In addition, certain conjugation and chemistry activities for vaccines are performed at our Emeryville, California site. Our diagnostics products are manufactured for us by outside suppliers. The division's predecessor, Chiron, experienced supply interruptions in the past, and there can be no assurance that supply will not be interrupted again in the future as a result of unforeseen events. The manufacture of our products is heavily regulated which means that supply can never be an absolute certainty. If we or our suppliers fail to comply fully with such regulations then there could be a product recall or government-enforced shutdown of production facilities which in turn could lead to product shortages.

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 or other requirements. We monitor market developments that could

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have an adverse effect on the supply of essential materials. All raw materials we purchase must comply with our quality standards.

Each year new influenza vaccines need to be produced in order to confer effective protection against the current circulating strains of the virus, which can change from year to year. Global surveillance of influenza viruses is conducted throughout the year by the World Health Organization (WHO) Influenza Surveillance Network, which provides us with information on currently circulating strains and identifies the appropriate strains to be included in next season's influenza vaccine. Each year, the European Medicines Agency and the US Centers for Disease Control then confirm the vaccine composition for the coming season for the northern hemisphere and the Australian Therapeutic Goods Administration for the southern hemisphere. There can be no guarantee that the division will succeed in producing and having approved an updated flu vaccine within the timeframes necessary to commercialize the vaccine for the applicable flu season.

Marketing and Sales

Our main Vaccines marketing and sales organizations are based in Germany, UK, Italy and the US. We are also expanding operations in China and India, as well as in various other European countries. In the US, we market influenza and rabies vaccines through a network of wholesalers and distributors as well as direct to key customers. Direct sales efforts are focused on public health and distributor channels, and on non-traditional channels, such as employers, chain drug headquarters and service providers.

The Diagnostics marketing and sales efforts are focused exclusively on blood banks. With roughly half of worldwide blood donations not being subjected to updated viral nucleic acid screening, the company will focus on increasing the practice of viral nucleic acid screening using its proprietary systems in emerging areas of the world.

Competition

The global market for products of the type sold by our Vaccines and Diagnostics Division is highly competitive, and we compete against other major international corporations with substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

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 products.

Regulation

Our vaccines products are subject to essentially the same regulatory procedures as are the products of our Pharmaceuticals Division. See "Pharmaceuticals Regulation." In the US, a company seeking approval of a vaccine submits a Biologics License Application (BLA) for the vaccine, rather than an NDA. Subsequently, the BLA follows substantially the same path for approval as does an NDA. In addition, new registrations for seasonal flu vaccines must be validated and submitted every year, based on the influenza strains provided by WHO and the Centers for Disease Control and Prevention needed for the growth of the vaccine.

Diagnostics products are regulated as medical devices in the US and the EU. These jurisdictions each have risk-based classification systems that determine the type of information which must be provided to the local regulators in order to obtain the right to market a product. In the US, safety and effectiveness information for Class II and III devices must be reviewed by the FDA. There are two review procedures: a Pre-Market Approval (PMA) and a Pre-Market Notification (510(k)) submission. Under a PMA, the manufacturer must submit to the FDA supporting evidence sufficient to prove the safety and effectiveness of the device. The FDA has 180 days to review a PMA. Under Pre-Market Notification (510(k)), the

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manufacturer submits notification to the FDA that it intends to commence marketing the product, with data that establishes the product as substantially equivalent to another product already on the market. The FDA has 90 days to review and clear a 510(k) submission. For specific diagnostics products that are sold into blood banks, or sold for diagnosis of HIV-1 infection, applications are submitted for review by the FDA's Center for Biologics Evaluation and Research (CBER). Under such review, the product is considered a biologic until such time as approval is received, at which time the product becomes a medical device. For products used specifically for screening of blood donors, or biologic reagents sold for further manufacturing use, the medical device is subject to Licensure by CBER. The submission for this purpose follows the same requirements as Vaccines; a Biologic License Application is submitted to CBER. CBER has 240 days to review a BLA.

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

Intellectual Property

We attach great importance to patents, trademarks, 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.

SANDOZ

Our Sandoz Division is a world leader in developing, manufacturing and marketing generic pharmaceutical products, follow-on biopharmaceutical products and drug substances that are no longer protected by valid and enforceable patents. As of December 31, 2008, affiliates of the Sandoz Division employed 23,146 associates worldwide in more than 130 countries. In 2008, our Sandoz Division achieved consolidated net sales of $7.6 billion, 18% of the Group's total net sales.

The Sandoz Division is active in Retail Generics, Anti-Infectives and Biopharmaceuticals. In Retail Generics, we develop and manufacture active ingredients and finished dosage forms of pharmaceuticals no longer protected by patents, as well as supplying active ingredients to third parties. In Anti-Infectives, we develop and manufacture off-patent active pharmaceutical ingredients and intermediates mainly antibiotics for use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, we develop and manufacture protein- or other biotechnology-based products no longer protected by patents (known as biosimilars or follow-on biologics) and sell biotech manufacturing services to other companies.

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The worldwide market for generic pharmaceutical products has been growing by about 10% annually and is expected by industry analysts to continue at nearly that rate through 2013, fueled primarily by the growing health needs of an aging population, opportunities created through patent expiries, increasing access to healthcare and pressures to contain healthcare costs. According to IMS Health, Sandoz is the No. 2 company in worldwide generic sales and is positioned as a global leader in Retail Generics. Sandoz Biopharmaceuticals has emerged as a leader in biosimilars, with two marketed medicines based on precedent-setting approvals, a third medicine having received a positive opinion from the EU's CHMP, and a pipeline of two dozen projects at various stages of development. In addition, Sandoz remains one of the leading manufacturers of antibiotics worldwide.

Sandoz has three strategic priorities: to be first-to-market with our products as originators' patents expire or become unenforceable, to be cost competitive by leveraging our economies of scale in development and production, and to differentiate Sandoz based on our extensive global reach and our advanced technical expertise in the development and manufacturing of difficult-to-make generics and biosimilars.

In 2008, despite a limited number of new product launches, particularly in the US, Retail Generics benefited from key product launches including clopidogrel (Plavix®/Iscover®) in Germany. Anti-Infectives had continued volume growth and favorable pricing for active ingredients, offset partially by currency losses on sales denominated in US dollars but manufactured in Europe. Biopharmaceuticals grew as Sandoz continued to roll out important follow-on products and to expand contract manufacturing. Following the launch in Germany in 2007 of *Epoetin alfa Hexal* and *Binocrit, we* continued to roll out *Binocrit* in key European markets throughout 2008. Our recombinant human growth hormone *Omnitrope,* the first follow-on for this product to receive US and EU approvals, was also introduced in the US and major European markets in 2008 in a new, more patient-friendly liquid pen form, following the initial launch in 2006-2007.

In 2006, a Sandoz affiliate signed a binding Memorandum of Understanding regarding an exclusive collaboration with Momenta Pharmaceuticals, Inc., a biotechnology company specializing in the characterization and engineering of complex pharmaceuticals, to develop complex generics and follow-on biotechnology pharmaceuticals. As part of the arrangement, we purchased approximately 4.7 million shares of Momenta common stock for an aggregate price of $75 million. In June 2007, the Memorandum of Understanding was replaced by a definite Collaboration and License Agreement. Sandoz and Momenta intend to jointly develop, manufacture and commercialize four drug candidates, sharing profits from the sales under separate arrangements for each project. The companies also have agreed on a right of first negotiation for certain other projects concerning complex generic and follow-on product candidates for inclusion in the collaboration. In 2008, the FDA accepted for review our ANDA for glatiramer acetate, a generic version of Copaxone®, which was developed in collaboration with Momenta.

Recently Launched Products

Sandoz launched a number of important products in 2008, including:

Omnitrope, a follow-on version of the recombinant human growth hormone Somatropin®, was launched in the Liquid Pen version (5 and 10 mg) in the US, France and Italy.

Binocrit, a follow-on version of the recombinant human protein Eprex®/Erypo® for the treatment of anemia, was launched in the UK and France.

Cetirizine hydrochloride/pseudoephridine hydrochloride, a generic version of the antihistamine/decongestant combination Zyrtec-D®, was launched in the US.

Clopidogrel, a generic version of the anti-coagulant Plavix®/Iscover®, was launched in Germany.

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Risperidone, a generic version of the anti-psychotic product Risperdal®, was launched in France and Germany.

Lansoprazole, a generic version of the proton pump inhibitor Lanzor®/Prevacid®, was launched in France.

Amlodipine, a generic version of the anti-hypertensive Norvasc®, was launched in Japan and Italy.

Atorvastatin, a generic version of the anti-cholesterol product Lipitor®, was launched in Turkey.

Omeprazole, a generic version of the proton pump inhibitor Losec®/Prilosec®, was launched in Italy.

Ramipril, a generic version of the ACE inhibitor Tritace®/Ramace® or Altace®, was launched in Italy.

Key Marketed Products

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

Retail Generics

Product	Originator Drug	Description
Omeprazole	Prilosec®	Ulcer and heartburn treatment
Amoxicillin/clavulanic acid	Augmentin®	Anti-infective
Metoprolol	Lopressor®	Anti-hypertension
Fentanyl	Duragesic®	Analgesic
Amlodipine/Benazepril	Lotrel®	Hypertension
Simvastatin	Zocor®	Cholesterol lowering treatment
Acetylcysteine	Fluimucil®	Respiratory System
Ketoprofen	Orudis®	Analgesic
Azithromycin	Zithromax®	Anti-infective
Amoxicillin	Amoxil®	Anti-infective

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Anti-Infectives

Active Ingredients	Description
Oral and sterile penicillins	Anti-infectives
Oral and sterile cefalosporins	Anti-infectives
Clavulanic acid and mixtures with clavulanic acid	ß-lactam inhibitors
Classical and semisynthetic erythromycins	Anti-infectives
Tiamuline	Anti-infectives
Lovastatin, Simvastatin, Pravastatin	Statins
Vancomycin	Anti-infectives
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.

Biopharmaceuticals

Product	Originator Drug	Description
Omnitrope	Somatropin®	Recombinant human growth hormone
Binocrit and *Epoetin alfa Hexal*	Eprex®/Erypo®	Recombinant protein used for anemia

Principal Markets

The two largest generics markets in the world the US and Europe are the principal markets for Sandoz, although we are active in more than 130 countries. This table sets forth aggregate 2008 net sales by region:

Sandoz	2008 Net sales to third parties	
	($ millions)	(%)
United States	1,766	24
Americas (except the United States)	546	7
Europe	4,481	59
Rest of the World	764	10
Total	**7,557**	**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

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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 39 production facilities around the world. Among these, our principal production facilities are located in Barleben, Germany; Kundl, Austria; Menges and Ljubljana, Slovenia; Broomfield, Colorado; Wilson, North Carolina; Stryków, Poland; Kalwe and Mahad, India; Buenos Aires, Argentina; Boucherville, Canada; Cambé and Taboão, Brazil; Gebze and Syntex, Turkey. In 2007, we restructured our worldwide production network with the sale of our facility in Hvidovre, Denmark, and the acquisition of production sites in Gebze, Turkey, Zhongshan, China, and Jakarta, Indonesia. Although no longer part of our production capacity, we intend to retain a close relationship with the Radebeul, Germany site, which will remain one of our key suppliers.

Active pharmaceutical ingredients are manufactured in our own facilities or purchased from third-party suppliers. We maintain state-of-the-art and cost-competitive processes within our own production network. Those processes include fermentation, chemical syntheses and precipitation processes, such as sterile processing. Many follow-on biologics are manufactured using recombinant DNA derived technology by which a gene is introduced into a host cell, which then produces the human protein. This manufacturing process requires sophisticated technical expertise. We are constantly working to improve current and develop new manufacturing processes.

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 or other requirements. We monitor market developments that could have an adverse effect on the supply of essential active pharmaceutical ingredients. All active pharmaceutical ingredients we purchase must comply with high quality standards.

We obtain agricultural raw materials 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.

The goal of our supply chain strategy is to produce and distribute high quality products efficiently. 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 product recalls or a government-enforced shutdown of production facilities, which in turn could lead to product shortages. We have experienced supply interruptions in the past and there can be no assurance that supply will not be interrupted again in the future as a result of unforeseen circumstances. For example, in August 2008, our Wilson, North Carolina facility received a Warning Letter from the FDA which remains unresolved. The Warning Letter raises concerns regarding the Wilson facility's compliance with FDA Good Manufacturing Practice regulations, and states that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending NDAs, abbreviated NDAs or export certificate requests submitted by our Sandoz US affiliate. Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet highest quality standards. Voluntary recalls were made in the fourth quarter of 2008 as part of the FDA review of the facility.

Marketing and Sales

The Retail Generics business of Sandoz sells a broad portfolio of generic pharmaceutical products to wholesalers, pharmacies, hospitals and other healthcare outlets. Sandoz adapts its marketing and sales approach to local decision making processes, depending on the structure of the market in each country.

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In response to rising healthcare costs, many governments and private medical care providers, such as health maintenance organizations, have instituted reimbursement schemes that favor the substitution of generic products for bioequivalent branded pharmaceutical products. In the US, statutes have been enacted by virtually all states that permit or require pharmacists to substitute a less expensive generic product for the brand-name version of a drug which has been prescribed to a patient. Generic use is growing in Europe, but penetration rates in many EU countries are below those in the US because reimbursement practices do not create efficient incentives for substitution. Legislative or regulatory changes can have a significant impact on our business in a country. In Germany, for example, the generic market is in transition as healthcare reforms shift decision making from physicians to insurance funds.

Our Anti-Infectives business supplies Retail Generics and the pharmaceutical industry worldwide with active pharmaceutical ingredients and intermediates, mainly in the field of antibiotics.

Our Biopharmaceuticals business operates in an emerging business environment. Regulatory pathways for approving follow-on biologics are either new or still in development, and policies have not yet been defined for substitution and reimbursement of biosimilars in many markets, including the US.

Competition

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

In addition, research-based pharmaceutical companies have responded to increased competition from generic products by licensing their branded products to generic companies (the so-called "authorized generic"). By doing so, research-based pharmaceutical companies participate in the conversion of their branded product once generic conversion begins. 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. In the US, the authorized generic is not subject to the US Hatch-Waxman Act rules regarding exclusivity (See " Regulation"). The company that launches an authorized generic typically enters the market at the same time as the generic exclusivity holder. This tends to reduce the value of the exclusivity for the company that invested in creating the first generic. Furthermore, certain research-based companies continually seek new ways to protect their market franchise and to decrease the impact of generic competition. For example, some research-based pharmaceutical companies have recently reacted to generic competition by decreasing the prices of their branded product, thus seeking to limit the profit that the generic companies can earn on the competing generic product.

Development and Registration

Before a generic pharmaceutical may be marketed, intensive technical and clinical development work must be performed to demonstrate in bio-availability studies the bio-equivalency of the generic product to the reference product. Nevertheless, research and development costs associated with generic pharmaceuticals are much lower than those of the established counterparts, as no Phase I to Phase III clinical trials must be performed by the generic company. As a result, pharmaceutical products for which the patent and data exclusivity period has expired can be offered for sale at prices much lower than those of products protected by patents and data exclusivity, which must recoup substantial basic research and development costs through higher prices over the life of the product's patent and data exclusivity period.

For follow-on protein products, the regulatory pathways for approving such products are still in development in many countries. However, at least for certain biopharmaceutical products, at least some

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clinical trials do appear to be required. Nonetheless, Sandoz has successfully registered and launched the first biosimilar product in Europe and the US, as well as a second product in Europe.

Currently, the affiliates of the Sandoz Division employ more than 1,000 Development and Registration staff who explore alternative routes for the manufacture of known compounds and develop innovative dosage forms of well-established medicines. These associates are based worldwide, including major facilities in Holzkirchen and Rudolstadt, Germany; Kundl and Schaftenau, Austria; Menges and Ljubljana, Slovenia; Kolshet, India; Boucherville, Canada; Wilson, North Carolina; Cambé, Brazil and Buenos Aires, Argentina.

In 2008, Sandoz invested $667 million in product development, which amounted to 8.8% of the division's net sales. Our Sandoz Division invested $563 million and $477 million in product development in 2007 and 2006 respectively.

Regulation

The Hatch-Waxman Act in the US (and similar legislation in the EU and in other countries) eliminated the requirement that generic pharmaceutical manufacturers repeat the extensive clinical trials required for originator products, so long as the generic version could be shown in bioavailability studies to be of identical quality and purity, and to be biologically equivalent to the reference product.

In the US, the decision whether a generic pharmaceutical is bioequivalent to the original branded product is made by the FDA based on an Abbreviated New Drug Application (ANDA) filed by the generic product's manufacturer. The process typically takes 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 product does not infringe on any current applicable patents on the product held by the innovator, or to certify that such patents are invalid or the product is non-infringing. This certification often results in a patent infringement lawsuit being brought by the patent holder against the generic company. In the event of such a lawsuit, the Hatch-Waxman Act imposes an automatic 30-month delay in the approval of the generic product in order to allow the parties to resolve the intellectual property issues. For generic applicants who are the first to file their ANDA containing a certification claiming non-infringement or patent invalidity, the Hatch-Waxman Act provides those applicants with 180 days of marketing exclusivity to recoup the expense of challenging the innovator patents. However, amendments to the Hatch-Waxman Act may affect the availability of generic marketing exclusivity in certain circumstances. The 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 the granting of a marketing authorization are made either by the EMEA under the Centralized Procedure, or by a single Member State under the national or decentralized procedure. See " Pharmaceuticals Regulation European Union." Companies may submit Abridged Applications for approval of a generic medicinal product based upon its "essential similarity" to a medicinal product authorized and marketed in the EU following the expiration of the product's data exclusivity period. In such cases, the generic company is able to submit its Abridged Application based on the data submitted by the medicine's innovator, without the need to conduct extensive Phase III clinical trials of its own. According to recent legislation, for all products that received a marketing authorization in the EU after late 2005, the Abridged Application can be submitted throughout the EU. However, the data submitted by the innovator in support of its application for a marketing authorization for the reference product will be protected for ten years after the first grant of marketing authorization in all Member States, and can be extended for an additional year if a further innovative indication has been authorized for that product, based on pre-clinical and clinical trials filed by the innovator that show a significant clinical benefit in comparison to the existing therapies. Because this recent legislation extended the

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ten-year protection period throughout the EU and offered the opportunity for an extension of the existing data protection period, it is possible that future launches of generic products will be delayed in certain EU countries.

Intellectual Property

Wherever possible, our generic 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 also may 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 take the position that their intellectual property rights have been infringed by the introduction of our generic products, and assert patent and other intellectual property rights against us. 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.

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 consumers. The business of Consumer Health is conducted by a number of affiliated companies throughout the world. Created in January 2002, the Consumer Health Division's continuing operations consists of the following three business units:

Over-the-Counter (OTC)

Animal Health

CIBA Vision

As of December 31, 2008, the affiliates of our Consumer Health Division continuing operations employed 13,014 associates worldwide. In 2008, the affiliates of our Consumer Health Division achieved consolidated net sales from continuing operations of $5.8 billion, which represented 14% of the Group's total net sales from continuing operations.

Our Consumer Health Division places considerable emphasis on the development of strong, consumer-oriented and trustworthy brands. 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 needs and desires of consumers.

In the dynamic world of consumer healthcare, consumers are becoming more knowledgeable about health and the benefits of self-medication. The success of each business unit depends upon its ability to anticipate and meet the needs of consumers and health professionals worldwide.

The Medical Nutrition and Gerber Business Units were previously included in the Consumer Health Division, but have been classified as discontinued operations in all periods in the Group's consolidated financial statements, as a consequence of the divestment of these business units. On September 1, 2007, we completed the sale of the Gerber Business Unit to Nestlé S.A., Switzerland for $5.5 billion. On July 1, 2007, we completed the sale of the remainder of the Medical Nutrition Business Unit to Nestlé S.A., Switzerland for $2.5 billion. On February 17, 2006, we completed the sale of Nutrition & Santé for $211 million to ABN AMRO Capital France.

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The following is a description of the three Consumer Health Division Business Units:

Over-the-Counter (OTC) is a world leader in offering products for the treatment and prevention of common medical conditions and ailments, to enhance people's overall health and well-being. The business of OTC is conducted by a number of affiliated companies in more than 45 countries. The OTC business focuses on a group of strategic global brands in leading product categories that include cough/cold/respiratory treatments (*Triaminic* and *TheraFlu/NeoCitran*), pain relief (*Excedrin*, *Voltaren*), lifestyle treatments, including gastrointestinal (*Benefiber,*) and smoking cessation treatments (*Habitrol/Nicotinell*), and dermatological treatments (*Lamisil AT*). In addition, preparations are underway for the expected launch of an over-the-counter version of the blockbuster prescription drug Prevacid®, one of the leading prescription medicines currently used to treat a number of acid related disorders including heartburn. Over-the-counter Prevacid is expected to become Novartis OTC's second biggest brand, after OTC *Voltaren*, based on projected sales.

Animal Health offers products and services to save, prolong and improve animal lives, focusing on both companion and farm animals (including cultivated fish). The business of Animal Health is conducted by affiliated companies in 38 countries. Animal Health has a dedicated research and development team, which benefits from synergies with other Novartis businesses, most notably research in the Pharmaceuticals Division. Key products for companion animals include *Atopica* (atopic dermatitis management), *Deramaxx* (pain relief) and *Sentinel/Milbemax/Interceptor* (intestinal parasite control and heartworm prevention), while leading farm animal products include the farm fly control product *Agita* and the therapeutic anti-infective *Denagard*, an effective broad-spectrum antimicrobial used to treat and control bacteria in swine. Aquaculture products include vaccines and treatments mainly used in salmon farming. In March 2007, we completed the acquisition of the Japanese animal health business of Sankyo Lifetech Co., Ltd., expanding our presence in Japan, particularly in the rapidly-growing companion animal segment.

CIBA Vision is a global leader in the research, development, and manufacturing of contact lenses and lens care products. The business of CIBA Vision is conducted by affiliated companies in nearly 40 countries. CIBA Vision is committed to the research and development of innovative products, processes and systems. R&D efforts have produced lenses such as the *Air Optix* family of silicone hydrogel lenses, and *Dailies* daily disposable lenses. CIBA Vision is also the world's leading provider of color contact lenses to change and enhance eye color through products such as *FreshLook* lenses. In lens care, CIBA Vision has developed many innovative products, particularly multi-purpose solutions in one bottle such as *Aquify/Solocare Aqua* and the *Clear Care/Aosept Plus* peroxide system.

Principal Markets

The principal markets for the Consumer Health Division are the US and Europe. The following table sets forth the aggregate 2008 net sales of the Consumer Health Division by region:

Consumer Health	**2008 Net sales to third parties**	
	($ millions)	**(%)**
United States	1,714	29
Americas (except the United States)	503	9
Europe	2,732	47
Rest of the World	863	15
Total net sales	**5,812**	**100**

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Sales of our OTC Business Unit are marked by a high degree of seasonality, with our cough, cold and allergy brands significantly affected by the timing and severity of the annual cold and flu and allergy seasons. Sales of our Animal Health Business Unit's livestock segment can also fluctuate seasonally, and can be significantly affected by climatic and economic conditions, or by changing health or reproduction rates of animal populations. Sales of most of our other products are not subject to material changes in seasonal demand.

Production

OTC: Products for our OTC Business Unit are produced by the business unit's own plants, strategic third-party suppliers 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.

Animal Health: Approximately 80% of our production volume is manufactured by third parties and Novartis affiliates in other divisions or 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; Charlottetown, Canada; and Huningue, France.

CIBA Vision: CIBA Vision has major production facilities in Batam, Indonesia; Duluth, Georgia; Des Plaines, Illinois; Grosswallstadt, Germany; Cidra, Puerto Rico; Singapore; Johor, Malaysia; and Mississauga, Canada. In 2008, CIBA Vision significantly streamlined its production processes, resulting in consistently high fulfillment rates.

While production practices may vary from business unit to business unit, we generally 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. To limit the volatility of prices charged to us for raw materials, where practical and beneficial, we make use of long-term supply agreements. We also proactively monitor markets and developments that could have an adverse effect on the supply of essential materials.

The goal of our supply chain strategy is to produce and distribute high quality products efficiently. 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 product recalls or a government-enforced shutdown of production facilities, which in turn could lead to product shortages. Some of our production facilities are unionized, including some CIBA Vision facilities. CIBA Vision has experienced significant supply interruptions in the past and there can be no assurance that CIBA Vision's supply or the supply of OTC or Animal Health will not be interrupted again in the future as a result of unforeseen circumstances.

Marketing and Sales

OTC: OTC aims to be a leading global participant in fulfilling the needs of patients and consumers for self-medication healthcare. Strong, leading brands and products, innovation led by a worldwide research and development organization, and in-house marketing and sales organizations are key strengths in pursuing this objective. We engage in general public relations activities, including media advertisements, brand websites and other direct advertisements of brands, to the extent permitted by law in each country. We distribute our products through various channels such as pharmacies, food, drug and mass retail outlets.

Animal Health: Animal Health's products are mostly prescription-only treatments for both farm and companion animals. The major distribution channel is veterinarians either directly or through wholesalers of veterinary products. Primary marketing efforts are targeted at veterinarians using such marketing tools as targeted personal selling, printed materials, direct mail, advertisements, articles in the veterinary specialty press, and conferences and educational events for veterinarians. In addition, we engage in

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general public relations activities and media advertising, including brand websites and other direct advertisements of brands, to the extent permitted by law in each country.

CIBA Vision: In most countries, contact lenses are available only by prescription. CIBA Vision lenses can be purchased from eye care professionals, optical chains and large retailers, subject to country regulation. CIBA Vision's lens care products can be found in major drug, food, mass merchandising and optical retail chains in the US, Europe, Japan and elsewhere subject to country regulations. In addition, mail order and Internet sales of contact lenses are becoming increasingly important channels in major markets worldwide.

Competition

The global market for products of the type sold by our Consumer Health Division is highly competitive, and we compete against other major international corporations with substantial financial and other resources. Competition within the industry is intense and extends across a wide range of commercial activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

Research and Development

OTC: In OTC, the focus of research and development activities is primarily on dermatology, analgesics, cough/cold/respiratory, gastrointestinal, 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.

Animal Health: Novartis Animal Health has dedicated research and development facilities in Switzerland, North America and Australia. The main focus for research is identification of potential new parasiticides and therapeutics in key areas of internal medicine. In addition, in the US and Canada, we devote resources to the quest for new vaccines for farm animals and cultivated fish. Also, our researchers exploit synergy with other Novartis businesses and collaborate with external partners to develop veterinary therapeutics and vaccines. Drug delivery projects, some in collaboration with external partners, concentrate on key treatment areas and aim to improve efficacy and ease of use.

CIBA Vision: CIBA Vision invests substantially in internal research and development operations, which yield new chemistries, lens designs and surfaces, and processing technologies. These resources are complemented by licensing agreements and joint research and development partnerships with third parties. For contact lenses our key focus is in two areas: daily disposable lenses and silicone hydrogel lenses. In lens care, our development efforts focus on lens care solutions that complement silicone hydrogel contact lenses, and provide the safety, disinfecting and cleaning power needed to help maintain ocular health.

In 2008, the Consumer Health Division continuing operations invested $313 million in research and development, which amounted to 5.4% of the division's net sales. Our Consumer Health Division invested $301 million and $260 million on research and development in 2007 and 2006 respectively,

Regulation

OTC: 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

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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.

Animal Health: 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 target animal and user safety, environmental fate and toxicology, efficacy in laboratory and clinical studies, information on manufacturing, quality control and labeling as well as on residues and food safety if applied to food-producing animals. 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, Mutual Recognition Procedure or the Decentralized Procedure. See " Pharmaceuticals Regulation."

CIBA Vision: Contact lenses and lens care products are regulated as medical devices in the US, the EU and the majority of other regulated countries. In the US, extended wear contact lenses are considered Class III devices, for which a PMA application is submitted to FDA. Daily wear lenses and lens care products are considered Class II devices for which the manufacturer must submit a Premarket Notification 510(k) application. See " Vaccines & Diagnostics Regulation."

Intellectual Property

Our Consumer Health businesses are strongly brand-oriented. As a result, 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.

Our Consumer Health businesses also sell 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.

In addition, see "Item 18. Financial Statements note 19" for a description of patent litigation involving the CIBA Vision Business Unit of our Consumer Health Division.

4.C Organizational Structure

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

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4.D Property, Plants and Equipment

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

We generally own our facilities. However, a few sites are leased under long-term leases. Some of our principal facilities are subject to mortgages and other security interests granted to secure indebtedness to certain financial institutions. We believe that our production plants and research facilities are well maintained and generally adequate to meet our needs for the foreseeable future.

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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		
Ringaskiddy, Ireland	532,000	Drug substances, intermediates
Grimsby, UK	450,000	Drug substances, intermediates
Stein, Switzerland	358,000	Steriles, ampules, vials, tablets, capsules, transdermals
Basel, Switzerland Klybeck	235,000	Drug substances, intermediates
Basel, Switzerland Schweizerhalle	230,000	Drug substances, intermediates
Basel, Switzerland St. Johann	225,000	Drug substances, intermediates, biopharmaceutical drug substance
Torre, Italy	200,000	Tablets, drug substance intermediates
Changshu, China	229,000	Drug substances, intermediates
Suffern, NY	61,000	Tablets, capsules, transdermals, vials
Kurtkoy, Turkey	51,000	Tablets, capsules, effervescents
Horsham, UK	14,400	Tablets, capsules
Sasayama, Japan	104,000	Tablets, capsules, dry syrups, suppositories, creams, powders
Huningue, France	112,000 (includes Animal Health facilities)	Suppositories, liquids, solutions, suspensions, biopharmaceutical drug substances
Singapore	29,262	Bulk tablets
Wehr, Germany	58,000	Tablets, creams, ointments

Barbera, Spain	51,000	Tablets, capsules
Chang Ping, China	28,000	Tablets, capsules, gel

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Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Vaccines and Diagnostics		
Emeryville, CA	99,000 (production and R&D facilities; includes Pharmaceuticals facilities)	Vaccines and blood testing
Vacaville, CA	1,300	Diagnostic component; biopharmaceutical drug substance
Liverpool, UK	62,000	Influenza vaccines
Ankleshwar, India	11,000	Vaccines
Marburg, Germany	45,000 (production and R&D facilities)	Vaccines
Siena/Rosia, Italy	97,000 (production and R&D facilities)	Vaccines
Sandoz		
Taboão da Serra, Brazil	501,000	Capsules, tablets, syrups, suppositories, suspensions, creams, drop solutions, powders
Kundl and Schaftenau, Austria	449,000 (production and R&D facilities)	Biotech products, intermediates, active drug substances, final steps (finished pharmaceuticals)
Menges, Slovenia	131,000 (production and R&D facilities)	Biotech products and active drug substances
Barleben, Germany	95,000	Broad range of finished dosage forms
Ljubljana, Slovenia	83,000 (production and R&D facilities)	Broad range of finished dosage forms
Broomfield, CO	60,000	Broad range of finished dosage forms
Kalwe, India	47,000	Broad range of finished dosage forms

Mahad, India	43,000	Active drug substances
Gebze, Turkey	42,000	Broad range of finished dosage forms
Cambé, Brazil	32,000	Broad range of finished dosage forms

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Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Wilson, NC	31,000 (production and R&D facilities)	Broad range of finished dosage forms
Rudolstadt, Germany	23,000 (production and R&D facilities)	Inhalation technology, ophthalmics and nasal products
Stryków, Poland	20,000	Broad range of finished dosage forms
Kolshet, India	20,000 (production and R&D facilities)	Generic pharmaceuticals
Boucherville, Canada	14,350 (production and R&D facilities)	Injectable products
Consumer Health		
OTC		
Lincoln, NE	46,000 (production and R&D facilities)	Tablets, liquids, creams, ointments, capsules, patches
Nyon, Switzerland	15,000 (production and R&D facilities)	Liquids and creams
Humacao, Puerto Rico	8,000	Tablets, capsules, medicated chocolates, softgels and Thin Strips
Animal Health		
Wusi Farm, China	39,000	Insecticides, antibacterials, acaricides, powders
Larchwood, IA	13,000 (production and R&D facilities)	Veterinary immunologicals
Dundee, UK	11,000	Packaging, formulation of liquids, solids, creams, sterile filling
Braintree, UK	6,000	Veterinary immunologicals
Huningue, France	5,000	

		Formulation and packaging of tablets, creams, ointments, suspensions and liquids
Charlottetown, Canada	2,700	Veterinary immunologicals for aquaculture

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Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
CIBA Vision		
Johor, Malaysia	35,000	Contact lenses
Duluth, GA	34,000	Contact lenses
Pulau Batam, Indonesia	27,000	Contact lenses
Des Plaines, IL	27,000	Contact lenses
Singapore	19,000	Contact lenses
Cidra, Puerto Rico	6,000	Contact lenses
Toronto, Canada	15,000	Lens care products
Major Research and Development Facilities:		
Pharmaceuticals		
East Hanover, NJ	177,000	General pharmaceutical products
Basel, Switzerland St. Johann	150,000	General pharmaceutical products
Basel, Switzerland Klybeck	140,000	General pharmaceutical products
Cambridge, MA	88,000	General pharmaceutical products
Horsham, UK	38,000	Respiratory and nervous system diseases
Emeryville, CA	(included in Vaccines and Diagnostics facilities)	Oncology
Shanghai, China	5,000	Oncology
Vaccines and Diagnostics		
Emeryville, CA	99,000 (production and R&D facilities; includes Pharmaceuticals facilities)	Vaccines and blood testing
Siena/Rosia, Italy	97,000 (production and R&D facilities)	Vaccines

Marburg, Germany	45,000 (production and R&D facilities)	Vaccines
Cambridge, MA	8,500	Vaccines

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Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Sandoz		
Kundl and Schaftenau, Austria	449,000 (production and R&D facilities)	Biotech processes, innovations in antibiotic technologies
Menges, Slovenia	131,000 (production and R&D facilities)	Biotech products and active drug substances
Ljubljana, Slovenia	83,000 (production and R&D facilities)	Broad range of finished dosage forms and new delivery systems
Wilson, NC	31,000 (production and R&D facilities)	Broad range of finished dosage forms
Rudolstadt, Germany	23,000 (production and R&D facilities)	Inhalation technology, ophthalmics and nasal products
Holzkirchen, Germany	17,000	Broad range of innovative dosage forms, including implants and transdermal therapeutic systems
Boucherville, Canada	14,350 (production and R&D facilities)	Injectable products
Kolshet, India	20,000 (production and R&D facilities)	Generic pharmaceuticals
Consumer Health		
OTC		
Lincoln, NE	44,870 (production and R&D facilities)	Tablets, capsules, liquids, ointments, creams and high potent compounds
Nyon, Switzerland	15,000 (production and R&D facilities)	Over-the-counter medicine products
Thane, India	2,000 (R&D facilities)	Tablets, capsules, powders,creams, ointments, oral liquids
Animal Health		

St. Aubin, Switzerland	26,000	Parasiticides, therapeutics for companion and farm animals
Larchwood, IA	13,000 (production and R&D facilities)	Veterinary immunologicals

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Location/Division or Business Unit	Size of Site (in square meters)	Major Activity
Yarrandoo, Australia	3,000	Animal Health products
Basel, Switzerland	2,000	Animal Health products
CIBA Vision		
Duluth, GA	13,000	Vision-related medical devices
Grossostheim, Germany	4,000	Vision-related medical devices

Progress is being made in the long-term redevelopment of our St. Johann headquarters site in Basel, Switzerland. This project, called "Campus," was started in 2001 with the aim of transforming the site into a center of knowledge with a primary emphasis on international corporate functions and research activities. Research and Development now accounts for a greater proportion of our activities at the site, and therefore changes needed to be made to the Campus, since the site had been designed primarily for pharmaceuticals production. Through December 31, 2008, the total amount paid and committed to be paid on the Campus Project is $1.5 billion. We expect that, through 2015, we will spend more than $2.6 billion on the Campus and to transfer production facilities from the Campus to other sites in the Basel region. We intend to fund these expenditures from internally developed resources.

In 2007, our Pharmaceuticals Division opened a new pharmaceuticals manufacturing facility in Singapore. The plant manufactures solid dosage forms (tablets) of existing and new Novartis products. When fully operational, our investment in this facility is expected to total approximately $180 million. Also in 2007, we announced plans to invest in a new large-scale cell culture plant in Singapore. Following completion of the basic design of the facility in early 2008, the project was put on hold but could be resumed depending on the development of the biopharmaceutical pipeline.

In 2008, our Pharmaceuticals Division invested approximately $63 million in a new production facility in Changshu, China, mainly to support the production of *Tekturna/Rasilez*. Commercial production is expected to commence in 2009.

Pre-production activities have commenced in our recently-extended Pharmaceutical Plant in Chang Ping, China. The total investment in this upgraded facility is expected to be approximately $24 million. The plant will support supply of our malaria treatment *Coartem* to the World Health Organization (WHO), in addition to supplying the local Chinese market with a diverse product portfolio.

In April 2007, NIBR opened a start-up facility for our new R&D center in Shanghai, China. This 5,000 square meter laboratory is home to approximately 125 Research and Development scientists. In 2008, we broke ground on a new facility that will be home to approximately 400 R&D scientists and approximately 400 other Pharmaceuticals Division personnel. An initial investment of $100 million is planned for the construction of the two facilities.

In September 2008, the Vaccines and Diagnostics Division inaugurated its new virology research center in Cambridge, Massachusetts. This 8,500 square meter facility which houses a state-of-the-art BSL3 laboratory will be home to 220 Research and Development scientists. In June 2008, the division also broke grounds on a new rabies and tick-borne encephalitis manufacturing facility in Marburg, Germany which is expected to require a total investment of approximately $250 million. Work continued on the division's cell culture-based manufacturing site in Holly Springs, North Carolina. To date, the total amount spent on the project is $350 million. The total investment in this new facility is expected to be least $600 million, partly supported by grants from the US government.

In 2008, CIBA Vision closed the specialty lens manufacturing facility in Grosswallstadt, Germany, and moved the related operations to its production facility in Cidra, Puerto Rico.

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Environmental Matters

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

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

See also "Item 3. Key Information Risk Factors Environmental liabilities may impact our results of operations" and "Item 18. Financial Statements note 19."

Item 4A. Unresolved Staff Comments

Not applicable

Item 5. Operating and Financial Review and Prospects

5.A Operating Results

This operating and financial review should be read together with the Group's consolidated financial statements in this Form 20-F. The consolidated financial statements and the financial information discussed below have been prepared in accordance with IFRS as published by the IASB.

OVERVIEW

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

The Group's businesses are divided into four global operating divisions:

Pharmaceuticals: Innovative patent-protected pharmaceuticals

Vaccines and Diagnostics: Human vaccines and blood-testing diagnostics

Sandoz: Generic pharmaceuticals

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

Our strategy is to strengthen this healthcare portfolio through sustained investments in innovation as well as targeted acquisitions. In April 2008, Novartis announced an agreement with Nestlé S.A. providing the right to acquire 77% majority ownership of Alcon Inc. (NYSE: ACL), the world leader in eye care, in a two-step process. The potential value of these transactions is up to approximately $39 billion. In July 2008, the

first step was completed when Novartis acquired a 25% stake for $10.4 billion in cash. In the optional second step, Novartis has the right to acquire Nestlé's remaining 52% majority stake between January 1, 2010, and July 31, 2011, for a fixed price of $181 per share, or approximately $28 billion. During

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this period, Nestlé has the right to require us to buy its remaining stake at a 20.5% premium to Alcon's share price at that time, but not exceeding $181 per share. Novartis has no obligation to purchase the remaining 23% of shares held by Alcon minority shareholders.

Results from continuing operations in 2008, 2007 and 2006 exclude contributions from the Medical Nutrition and Gerber Business Units, which were divested in 2007 and resulted in a combined after-tax divestment gain of $5.2 billion. The sale of these businesses in separate transactions to Nestlé S.A. completed the divestment of remaining non-healthcare businesses. Both were previously included in the Consumer Health Division, but are now classified as discontinued operations in the consolidated financial statements.

Novartis achieved net sales of $41.5 billion in 2008 from continuing operations, up 9% (+5% in local currencies, or lc). Pharmaceuticals delivered accelerating growth while overcoming the 2007 challenges from the entry of generic competition for some products in the US and the suspension of *Zelnorm*. Important contributions from other businesses particularly Vaccines and Diagnostics and Consumer Health further supported the performance.

Operating income from continuing operations advanced 32% to $9.0 billion based on the solid business expansion and productivity gains from Forward, the Group-wide efficiency initiative launched in December 2007. Results in 2007 included approximately $1.0 billion of exceptional charges ($590 million for the Corporate environmental provision increase and $444 million in Forward restructuring charges). Excluding these two charges, operating income was up 15% in 2008.

Net income from continuing operations grew 25% to $8.2 billion, at a slower pace than operating income mainly due to an unusually low tax rate in 2007 as well as the start of financing costs in July 2008 for the 25% Alcon investment. Excluding the above exceptional charges in 2007, net income rose 11% in 2008. Basic earnings per share from continuing operations were up 28% to $3.59 from $2.81 in 2007 on fewer outstanding shares.

Headquartered in Basel, Switzerland, the Group employed approximately 96,700 full-time equivalent associates as of December 31, 2008, and has operations in approximately 140 countries around the world.

FACTORS AFFECTING RESULTS OF OPERATIONS

A number of key factors influence the Group's results of operations and the development of our businesses.

The global healthcare market is expected to continue growing due to long-term demographic and socioeconomic trends worldwide. Both in industrialized countries and emerging markets, the aging of the population, along with sedentary lifestyles and poor nutritional habits, are producing a rising incidence of chronic diseases. These and other factors are prompting greater use of medicines. At the same time, new medicines and healthcare products are being developed to better treat many diseases as a result of technological advances and consistent investments in innovation.

The growing burden of healthcare costs as a percentage of Gross Domestic Product in many countries, however, is placing intense pressure on governments and payors to control spending even more tightly. Deteriorating economic conditions are a complicating factor, and signs are emerging that the current economic slowdown may have a more negative impact on healthcare expenditures than in past recessions, in part due to the ongoing shift of costs to patients.

As a result, the healthcare industry operates in an ever-more challenging environment as government-controlled authorities around the world and managed-care providers in the US are stepping up actions to cut costs and restrict access to higher-priced new medicines. Some generic drug manufacturers, meanwhile, have become more aggressive in challenging intellectual property rights for patented medicines. At the same time, investments needed for the Research & Development of new medicines have risen dramatically, in part because of increasing scrutiny of drug safety and efficacy.

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In response to this fast-changing environment, Novartis has built up its presence in businesses that go beyond the traditional focus on patent-protected medicines. These areas include preventive vaccines and diagnostics, generic pharmaceuticals and consumer health products. We have invested heavily in all of these businesses through internal initiatives intended to drive organic growth as well as through acquisitions, and will continue to do so in the future.

Novartis believes this diversified portfolio focused solely on healthcare best addresses the needs of patients and customers, providing a broad range of products that offer important treatment benefits while helping to reduce overall healthcare costs. A growing number of patients, physicians and payors worldwide can benefit from this range of products offered by Novartis. These include new medicines seeking to offer improved efficacy and safety (Pharmaceuticals), preventive vaccines and diagnostic tools (Vaccines and Diagnostics), off-patent generic pharmaceuticals (Sandoz), and readily available products to support day-to-day health (Consumer Health).

This strategy also helps Novartis to mitigate the negative impact of economic challenges faced by healthcare systems and many patients, particularly in the area of patent-protected medicines. It also offers attractive opportunities for future growth in these attractive market segments.

Fundamental Drivers Remain Strong

With demographics and socioeconomic developments driving long-term growth in demand for healthcare, Novartis expects its businesses to keep expanding in the coming years, both in the established markets of the US, Western Europe and Japan, as well as in many emerging markets.

Aging Population Faces Increasing Healthcare Needs

The elderly represent a growing proportion of the world's population, a result of increasing life expectancy and declining birth rates. Nearly 500 million people worldwide were age 65 and older in 2006, and this number is expected to increase to one billion by 2030, according to a study published in 2007 by the US National Institute of Aging and the US Department of State. According to this study, the proportion of elderly people in the US is projected to rise to 13% from 8% by 2030, surpassing the number of children in the coming decade. In addition, the numbers of people over age 85 are increasing rapidly. While the elderly represent a greater percentage of the population in developed countries, older populations are generally growing more rapidly in the emerging markets. The increase in life expectancy is partly due to improved healthcare, but the aging of the population also creates increasing medical costs for governments, healthcare systems and patients since studies show the incidence of disease, and use of medicines, rises with age.

Novartis has many products in its portfolio that could provide benefits to the aging population by treating diseases and conditions that disproportionately afflict this group, including cardiovascular disease, cancer, Alzheimer's disease, osteoporosis, age-related macular degeneration and seasonal influenza.

Emerging Markets Grow Faster than Developed Countries

At a time of slowing pharmaceuticals sales growth in many industrialized countries, the longer-term economic expansion in several emerging markets has led to higher growth rates and an increasing contribution to the industry's global performance. According to IMS Health, a leading provider of industry information, the global pharmaceuticals market (both patent-protected and generic pharmaceuticals) is expected to grow 4.5-5.5% in 2009, at a similar pace compared to 5-6% in 2008. However, the 2009 forecast is slower than the 6-7% seen in 2007, and also below growth rates in previous years. The industry's sales in 2009 are expected to exceed $820 billion.

Key trends of recent years including faster growth in emerging markets, tougher regulation and cost-control measures, and patent expirations for many top-selling branded drugs may become even more prominent in 2009 and the future.

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Among developed markets, the US the world's largest pharmaceuticals market is forecast by IMS to grow only 1-2% in 2009 to about $285 billion, due in part to economic conditions as well as patent expiries and fewer new product launches. The top five European countries (France, Germany, Italy, Spain and the United Kingdom) are forecast to grow 3-4% in 2009, tempered by the increasing use of health benefit assessments, government cost-containment efforts and economic conditions.

At the same time, the seven leading emerging markets Brazil, China, India, Mexico, Russia, South Korea and Turkey are forecast by IMS to grow in 2009 at a combined 14-15% pace to about $110 billion in annual sales. These countries are benefiting from increasing government spending as a percentage of Gross Domestic Product on healthcare as well as broader public and private funding to improve access to medicines.

Novartis continues to take actions to increase its presence in a number of high-priority emerging markets, particularly China, Russia, South Korea and Turkey in the Pharmaceuticals Division, while implementing new business models in other emerging markets. Emerging markets, which accounted for approximately 24% of the Group's net sales in 2008, are expected to make increasingly significant contributions to future long-term results of operations.

Lifestyle Changes Boost Prevalence of Chronic Illnesses

Economic growth and change in nutritional habits have led to changes in lifestyles, both in industrialized and emerging countries. Surveys show people in general have become more sedentary and have adopted dietary habits that have in turn increased the risks of disease. These trends have led to a rapid rise in the incidence of chronic illnesses such as obesity, cardiovascular disease, diabetes, cancer and lung disorders. A World Health Organization report in October 2008 noted that heart attacks and related problems remain the world's top killer, claiming 29% of people who die each year, followed by infectious diseases and cancer. Novartis offers many products to help patients with chronic diseases, and will continue to make significant R&D investments into new treatments.

Scientific Advances Drive the Discovery of New Medicines

Ongoing developments in technologies and the understanding of diseases are laying a foundation for the creation of new treatments for medical conditions for which none currently exist or where current treatment options are inadequate. R&D investments by the global pharmaceuticals industry have risen more than tenfold during the last 20 years, according to the US industry trade association PhRMA, leading to a significant increase in the number of drugs in development pipelines.

Based on recent advances in technologies, particularly the analysis of human genome data, the number of drugs in development is expected to rise further based on improving information about the role of specific genes and proteins in the human body. Like other research-based pharmaceutical companies, we are making major investments in these new technologies. These could have a fundamental effect on product development and, in turn, could affect future results of operations.

Increasingly Challenging Business Environment

While the overall healthcare market has grown steadily, the competitive operating environment is becoming even more challenging. Factors include increasing cost pressures from payors, the threat of patent expirations for leading products, a period of relatively low industry-wide R&D productivity and increasing scrutiny of drug safety by regulatory agencies. Novartis believes it is well-positioned to address these challenges.

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Pressure of Patent Expirations and Generic Competition

The pharmaceuticals industry faces a continuing high level of patent expirations, with branded products representing approximately $24 billion in combined annual sales set to lose patent protection in 2009, similar to levels seen in recent years, according to IMS Health.

Given the ongoing pressure of patent expirations, innovation is critical to the success of companies like Novartis. Sustainable growth can come only by discovering and developing new products that address unmet needs, are accepted by patients and physicians, and are reimbursed by payors. Our ability to gain regulatory approvals, and then successfully secure and defend intellectual property rights is particularly important for the Pharmaceuticals Division. The loss of exclusivity for one or more important product due to patent expiration, generic challenges, competition from new branded products or changes in regulatory status could have a material negative impact on the Group's results of operations.

Novartis takes active steps to defend its intellectual property rights, including initiating patent infringement lawsuits against generic drug manufacturers and, to a lesser degree, against other research-based pharmaceutical companies. Some generics manufacturers, however, are increasingly conducting "at risk" launches of products before final resolution of legal challenges for patent infringement.

In 2008, sales of four Novartis pharmaceutical products *Lotrel* (high blood pressure)*Lamisil* (fungal infections), *Trileptal* (epilepsy) and *Famvir* (viral infections) continued to lose sales following the start of generic competition in the US during 2007. As a result of generic competition, combined net sales for these products in the US declined from $2.6 billion in 2006 to $1.6 billion in 2007, and further to $536 million in 2008. This sharp reduction had an adverse effect on the results of operations of the Pharmaceuticals Division in 2007 and 2008.

Our three best-selling products *Diovan* (high blood pressure)*Gleevec/Glivec* and *Zometa* (both for cancers) could potentially face significant competition in the coming two to six years in various markets, particularly the US and Europe. Competition could come in a number of forms: patent challenges, the entry of generic versions of another medicine in the same therapeutic class, or the regular expiration of patents. In particular, the patent on our top-selling drug, *Diovan,* expires in major European Union countries during 2011 and in the US in September 2012. In addition, sales of *Diovan* may begin to erode earlier in certain EU countries and the US ahead of a competitor product, Cozaar®, becoming the first branded medicine in this therapeutic class to lose market exclusivity (EU: 2009, US: 2010). Similarly, zoledronic acid, the active ingredient in *Zometa* as well as in *Aclasta/Reclast* (osteoporosis), is currently the subject of US patent litigation, with the possibility of an "at risk" launch by one or more generic competitors as early as the end of 2010. The loss of exclusivity for any one of these products could have a material adverse effect on the Group's business, financial condition and results of operations.

In addition to *Zometa* and *Aclasta/Reclast,* key products in the Pharmaceuticals Division that are the subject of ongoing US patent litigation include *Femara* (breast cancer), *Lescol* (high cholesterol), *Focalin/Ritalin LA* (Attention Deficit/Hyperactivity Disorder) and *Comtan/Stalevo* (Parkinson's disease). The loss of exclusivity for some of these products could have a significant adverse effect on the results of operations of the Pharmaceuticals Division. In addition, *Neoral* (transplantation) and *Voltaren* (pain), which are still among the Pharmaceuticals Division's top-ten selling products and had combined net sales of $1.8 billion in 2008, have encountered generic competition for some time in many markets. Although these products continue to generate relatively stable results, future sales from these products may decline further, which in turn could have an adverse effect on the Pharmaceuticals Division's business, financial condition and results of operations.

Regulatory Approvals Drop and Scrutiny of Safety Rises

Although scientific advances continue to lead to breakthroughs for patients, the pharmaceuticals industry has suffered from a dearth of regulatory approvals for new drugs in recent years. For example, the FDA approved only 18 entirely new drugs (new molecular entities) in 2007, one of the lowest

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single-year totals since 1983, when there were 14 new approvals. New product approvals for the industry are expected to remain low, with only 25-30 new molecular entities slated for launch in 2009, which follows FDA approvals for 24 brand new medicines in 2008, according to IMS Health. This decline in productivity comes at a time when the worldwide pharmaceuticals industry is spending more than $40 billion each year on R&D activities.

Following widely publicized issues such as the Merck & Co. recall of its pain medicine Vioxx® in 2004, healthcare regulators are increasingly focusing on product safety and efficacy as well as the risk/benefit profile of developmental drugs. Regulators are requiring more clinical trial data, with a significantly higher number of patients and more detailed analyses. As a result, obtaining regulatory approvals has become more challenging for pharmaceutical companies. In addition, maintaining regulatory approvals has become increasingly expensive as companies are now required to gather far more detailed safety and other clinical data on products after approval.

Similar to our industry peers, Novartis has suffered setbacks in recent years in gaining regulatory approvals for new products as well as being able to keep products on the market, primarily in the Pharmaceuticals Division. For example, in March 2007, we received an "approvable" letter from the FDA regarding *Galvus* (diabetes), which required Novartis to conduct additional major clinical trials to obtain US regulatory approval. Although *Galvus* was subsequently approved in the EU, a resubmission for US approval is not planned. Separately, in the second half of 2007, *Prexige* (osteoarthritic pain) was withdrawn in Australia and the EU based on post-marketing reports of serious liver side-effects, including two deaths in Australia, allegedly associated with long-term uses of higher doses. This product was subsequently withdrawn from remaining markets during 2008.

Pressure to Reduce Drug Prices and Increase Access to Medicines

Prices for healthcare products, primarily patented medicines, continue to stir significant political debate in both industrialized and developing countries. These debates focus on the relative costs of medicines at a time of rapidly rising overall expenditures for healthcare and an economic slowdown. As a result, payors primarily government-controlled agencies as well as insurance companies and managed care organizations in the US have been exerting pressure for some time to cut prices, urging physicians to use more generics and restricting access to new medicines. Patients also are being forced to pay a larger contribution toward their own healthcare costs, which has limited the growth of patented pharmaceuticals in countries such as the US. At the same time, this trend has led to growth in the use of OTC and generic pharmaceuticals, market segments in which Novartis is one of the world leaders.

Other Novartis Businesses Face Competition

Businesses in the Novartis portfolio outside of the Pharmaceuticals Division also face their own challenges.

Sandoz

The strong longer-term growth outlook for the generic pharmaceuticals market and the ongoing loss of exclusivity for several important industry products can create significant opportunities for Sandoz, but competition in this industry is very intense. Sandoz believes it has competitive advantages based on leadership positions in the world's top generics markets, active in countries covering 90% of the world's population, as well as its track record in gaining regulatory approvals for "difficult-to-make" generics that apply advanced technologies or are challenging to manufacture.

However, many of the division's products are considered commodities, with multiple sellers competing aggressively on price. In addition, pressure is increasing in some markets, particularly Europe and the US, to further reduce prices for generic pharmaceuticals. These pressures stem both from

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government regulations and various distributors that are aggressively seeking to increase their profit margins at the expense of generics manufacturers.

Finally, a number of factors have tended to limit the availability or decrease the value of marketing exclusivity periods granted to generics companies in certain markets. These can be a significant source of revenue for generics companies, particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act. Among the negative factors are aggressive steps taken by branded pharmaceuticals companies to counter the growth of generics, and increased competition among generics companies to achieve these periods of exclusivity. Pricing pressures and efforts by competitors of Sandoz have had, and likely will continue to have, a negative influence on the Division's results of operations.

Vaccines and Diagnostics

In the Vaccines and Diagnostics Division, the demand for some products such as influenza vaccines is seasonal, while the demand for others such as pediatric combination vaccines depends upon birth rates in developed countries and emerging markets. Some vaccines that make an important contribution to the division's net sales and profits, particularly the key influenza vaccines, are considered commodities, meaning there are few therapeutic differences among products offered by a number of competitors. In addition, the seasonal influenza vaccine market suffered from price erosion in 2008 amid an oversupply of vaccines across the industry. The ability to develop differentiated, effective and safe vaccines, to gain approval for inclusion in national immunization recommendation lists, and to then consistently produce and deliver high-quality vaccines in time for the relevant disease seasons are critical to the success of this business.

Consumer Health

Consumer spending, economic conditions, intense competition and efforts in many countries to shift healthcare costs to patients are among factors influencing results in the Consumer Health Division, which relies on consumer acceptance and loyalty to leading products brands in order to generate growth. The OTC Business Unit, which ranks No. 4 in this segment, faces significant competition from other major healthcare companies as well as from growing use in the US of so-called "private label" brands (consumer products sold by major retailers under own-label brands). In Animal Health, changes in the number of companion animals being maintained in consumer households in key geographic regions (particularly the US and Europe) can influence results, while the farm animal business continues to be affected by the global farming crisis. In CIBA Vision, trends in the use of contact lenses are dependent upon various factors that include economic cycles, consumer acceptance of new and existing products, innovations in contact lens technologies and consumer preference in general for these products.

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

In recent years, the industries of which we are a part have become important targets of litigation around the world, especially in the US. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including product liability, commercial, employment and wrongful discharge, antitrust, securities, sales and marketing practices, health and safety, environmental and tax litigation claims, government investigations and intellectual property disputes. As a result, we may become subject to substantial liabilities that may not be covered by insurance. Litigation is inherently unpredictable, and large verdicts sometimes occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations or cash flows.

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Patent Litigation

Our Pharmaceuticals Division frequently defends its patents against challenges by our competitors. Should we fail to successfully defend our patents, we will be faced with generic competition for the relevant products, and a resulting loss of revenue.

At the same time, our Sandoz Division may, from time to time, seek approval to market a generic version of a product before the expiration of patents claimed by one of our competitors for the branded product. We do this in cases where we believe that the relevant patents are invalid, unenforceable, or would not be infringed by our generic product. As a result, we frequently face patent litigation, and in certain circumstances, we may elect to market a generic product even though patent infringement actions are still pending. However, these so-called "at-risk" launches could result in Sandoz facing substantial damages if we do not prevail in litigation.

The CIBA Vision Business Unit of our Consumer Health Division also has been required to defend its patents against frequent challenges by competitors.

Pricing Litigation

The US subsidiaries of our Pharmaceuticals and Sandoz Divisions are the subjects of separate lawsuits brought by private plaintiffs and state and local government entities alleging that they have fraudulently overstated the Average Wholesale Price and "best price," which are, or have been, used by the US federal and state governments in the calculation of, respectively, US Medicare reimbursements and Medicaid rebates. A limited number of similar actions have been brought to trial to date against various pharmaceutical companies, including one against our subsidiary in the Pharmaceuticals Division, and in certain instances, substantial damages have been awarded. Recent damage awards are on appeal. Should we fail to successfully defend the cases against us, we could face substantial damages if the final court decision is adverse to us.

Governmental Investigations

Governments and regulatory authorities have been stepping up their compliance and law enforcement activities in recent years in key areas, including corruption, marketing practices, antitrust and trade restrictions. Our businesses have been subject, from time to time, to such governmental investigations and information requests by regulatory authorities. For example, we are cooperating with civil and criminal investigations currently being undertaken by the US Attorney's Office into allegations of potential off-label promotion of our epilepsy drug *Trileptal*. While the outcomes of government and regulatory investigations are unpredictable, they are costly, divert management from our business and may affect our reputation. In some instances, the inherent uncertainty of litigation, the resources required to defend against governmental actions and the risk to reputation as well as of potential exclusion from US federal government reimbursement programs have contributed to decisions by companies in our industry to enter into settlement agreements with governmental, and particularly federal, authorities. Those settlements have involved and may continue to involve large cash payments, including the potential repayment of amounts allegedly obtained improperly and penalties up to treble damages. In addition, settlements of healthcare fraud cases typically involve corporate integrity agreements that are intended to regulate company behavior for a period of years. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

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

Novartis Strategies for Sustainable Growth

Novartis believes it has one of the best portfolios to address the demands of the dynamically changing healthcare environment.

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We are implementing longer-term strategic initiatives to create sustainable growth. Key actions include strengthening our healthcare portfolio, driving innovation through R&D investments, expanding in high-growth markets and improving operational efficiency.

Selectively Strengthen Healthcare Portfolio

Each of the four divisions is expected to play a significant role in the future success of the Group, providing opportunities for growth by offering a range of medicines and vaccines to patients, physicians and payors. We will continue to evaluate internal and external opportunities to improve the competitiveness of these businesses and better position the Group for success. The strong performances of the Vaccines and Diagnostics and Sandoz Divisions in recent years reflect the positive impact of significant investments. The focused diversification also helps to balance industry risks.

Innovative Medicines

The aim of the Pharmaceuticals Division is to provide patients and physicians with new and better medicines that deliver improved efficacy and fewer side-effects as well as to address unmet medical needs. Novartis ranks as one of the top 10 companies worldwide based on sales of patent-protected medicines, with leading positions in cardiovascular and cancer treatments and an expanding presence in neuroscience. Viewed as having one of the most respected pipelines in the industry, we will continue to invest heavily in Research & Development. We are also reviewing ways to more efficiently support new product launches by using new selling models and advanced marketing tools, particularly in the US and Europe. We are also committed to being a preferred partner for strategic alliances with biotechnology companies, both for development compounds and new technologies, and these collaborations will remain important to future business developments.

Prevention

The Vaccines and Diagnostics Division markets vaccines as well as blood-testing diagnostic tools that protect against many life-threatening diseases, providing access to the fast-growing human vaccines market. This division was created in April 2006 following the Group's acquisition of the remaining stake in Chiron Corporation not already held by Novartis. We further strengthened this business in September 2007 by entering into a strategic R&D alliance with Intercell, an Austrian biotechnology company focused on vaccines development.

Cost-Saving Alternatives

Sandoz markets generic products that replace branded medicines after patent expiry, providing cost-effective alternatives for patients, physicians and payors. With the acquisition in 2005 of two leading generic pharmaceuticals companies (Hexal AG and Eon Labs, Inc.), Sandoz became the world's second-largest generics company. Competitive advantages include strengths in difficult-to-make generics, particularly extended-release formulations of medicines and biosimilars (follow-on versions of previously approved biotechnology drugs). Given these capabilities, which provide access to higher-value areas of the generic pharmaceuticals market, Sandoz is expected to become an increasing contributor to our future results of operations.

Patient and Consumer Empowerment

The Consumer Health Division comprises the OTC, Animal Health and CIBA Vision Business Units, all of which provide high-quality consumer healthcare products with well-known brands. These businesses have gained market share in their respective segments through a focus on strategic brands, product innovation and expansion in emerging markets. While divesting non-healthcare activities, these three businesses have been strengthened through targeted acquisitions. For example, the North American rights

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to various OTC products were acquired in 2006 from Bristol-Myers Squibb Co., while the acquisition of Sankyo Lifetech's animal health business in Japan in 2007 expanded the geographic presence of Animal Health.

Step Up Innovation

Maintaining a competitive advantage in the healthcare industry requires significant R&D investments. The ability of Novartis to continue to grow all of our businesses and replace sales lost due to the end of exclusivity for important products depends upon the capability of the Group's R&D activities to identify and develop high-potential products and bring them quickly to market.

Like our competitors in the healthcare industry, Novartis will continue making significant investments in drug discovery. We are also taking steps to accelerate R&D activities throughout the Group and to find ways to lower attrition rates among pipeline products in the final stages before regulatory approvals. For example, a reorganization of the Pharmaceuticals Development organization that started in late 2007 has strengthened project focus, streamlined organizational structures and simplified decision-making processes.

Novartis has been building its innovative position by building capabilities and expertise in biologic therapies, which now represent 25% of our preclinical pharmaceuticals research portfolio. Biologic treatments, often referred to as "large molecules," are made from living cells and stimulate a response against specific disease targets. They often are intended to treat diseases that have been difficult to treat with "small molecule" medicines based on chemical substances. Novartis formed the Novartis Biologics Unit in 2007, establishing a dedicated innovation team with a strong biotech culture in the areas of discovery and development unique to biologics. The unit has full access to the extensive Novartis R&D organization and multiple therapeutic areas.

The quality of our current development pipeline reflects investments made in the Group's own R&D activities, in many cases more than 10-20 years ago, as well as recent acquisitions and licensing collaborations. We have consistently had one of the highest R&D investment rates as a percentage of net sales in the industry, reflecting our commitment to bringing innovative and differentiated products to patients with novel therapeutic benefits.

Our Pharmaceuticals Division uses up to one-third of its annual R&D expenditures to reach licensing agreements with other companies, particularly specialized biotechnology firms, to co-develop promising compounds. These collaborations enable us to capitalize on the potential of these compounds and to expand our development pipeline. Complementing internal R&D activities, Novartis (like other companies) has entered into a significant number of alliances in recent years. Equity investments are sometimes made in a licensing partner, or a decision is made to fully acquire a company to gain exclusive access to novel compounds. The industry-wide decline in R&D productivity in recent years, however, has led to increasing competition for collaborations with specialized players at the forefront of their fields. Funding requirements for R&D activities are likely to continue to grow in the future and are expected to continue rising at a faster rate than net sales. These investments, however, are critical to our continuing success. In 2008, we invested $7.2 billion in R&D activities throughout the Group, a 12% increase over 2007 and representing 17.4% of net sales.

Expand in High-Growth Markets

Novartis is expanding in high-growth markets around the world, particularly in a number of the seven leading countries of Brazil, China, India, Mexico, Russia, South Korea and Turkey identified by IMS Health as important to the healthcare industry. Even in light of the weakened economic conditions in some of these countries, these long-term investments are crucial to capturing market share and being well-positioned for the eventual economic recovery.

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Novartis has been taking significant actions to increase its presence in a number of these priority markets as well as adapting commercial models to better meet the needs of other emerging markets. A new cross-divisional operation was created in 2007 to accelerate growth in smaller emerging markets and better position the presence of all Novartis products. These areas include Northern and Sub-Saharan Africa, Central Asia and some countries in Southeast Asia. The Pharmaceuticals Division is also undertaking aggressive investments to accelerate growth in China, Russia, South Korea and Turkey, while Sandoz continues to expand its leadership in Central and Eastern Europe.

In 2008, Novartis generated approximately 64% (2007: 66%) of the Group's net sales from continuing operations in the world's seven largest developed markets, while 10% (2007: 9%) of net sales came from these seven leading emerging markets listed above. At the same time, combined net sales in these seven priority emerging markets grew 18% in local currencies (lc) in 2008 compared to 1% lc growth in the seven largest developed markets. Emerging markets in general accounted for approximately 24% of the Group's net sales in 2008 compared to 22% in 2007. As a result, emerging markets are expected to make increasingly significant contributions to our future results of operations.

Improve Organizational Efficiency

Novartis is constantly exploring ways to improve productivity. In particular, we are taking actions to improve our competitiveness in a fast-changing healthcare environment through Forward, a Group-wide initiative that has streamlined organizational structures and changed the way the Group operates. This initiative is expected to generate significant cost savings and help prepare Novartis for future growth. At the same time, we will continue investing in higher-value activities, particularly R&D in new biological therapies and expansion in key emerging markets.

As part of this initiative started in December 2007, Novartis has been streamlining and simplifying organizational structures in the corporate headquarters as well as in the Pharmaceuticals and Consumer Health Divisions. These initiatives have removed management layers, eliminated structural duplications and reduced resources used for general and administrative functions. We are also evaluating and optimizing supply networks worldwide. Initiatives are also progressing rapidly to standardize and streamline shared functions such as procurement, information technology and financial transaction processing to generate benefits in cost management and economies of scale. Some administrative activities also are being outsourced or transferred to lower-cost countries.

Through these initiatives, which are designed to maximize resources available to support ongoing profitable growth, the aim is to reduce the Group's cost base by approximately $1.6 billion by 2010 compared to 2007 levels. Annual cost savings of approximately $1.1 billion were achieved in 2008, exceeding the planned target of $670 million, mainly on the strength of accelerated procurement savings.

In order to implement these efficiency measures, Novartis recorded a restructuring charge of $444 million in 2007 that included plans for the reduction of approximately 2,500 full-time equivalent positions, or approximately 2.5% of the Group's worldwide workforce at the end of 2007. A majority of these reductions were achieved through natural attrition and vacancy management, with all of these actions done in a socially responsible manner.

Separate initiatives are underway to find more efficient marketing approaches to support new product launches. A strong marketing message and rapid penetration of multiple geographic territories are vital for a product to attain peak sales as quickly as possible before the loss of patent protection or the entry of competitive products. We continually evaluate our marketing models in the divisions and adjust the composition of sales forces, as appropriate.

As the US market becomes more complex, a new program called the Customer Centric Initiative was launched in October 2008 to implement a new regional US business model in the Pharmaceuticals Division that will better address customer needs and increasing differences among the needs of local markets. Five new regional units have been created with cross-functional responsibility for the full primary

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care product portfolio, replacing nationally managed sales forces. This new model is designed to be more effective at driving sales growth by better meeting the diverse and specific needs of customers as well as deploying resources more efficiently. As part of this initiative, approximately 550 full-time equivalent positions were eliminated in the US sales organization in a socially responsible manner, with more than half achieved by not filling vacant positions. The new organization started on January 1, 2009. A one-time charge of $19 million was taken in the fourth quarter of 2008, with annual cost savings of $80 million anticipated starting in 2010.

Acquisitions, Divestments and Other Significant Transactions

Novartis has made several acquisitions, strategic investments and divestments in recent years that have had a significant and ongoing impact on its financial condition and results of operations, see "Item 18. Financial Statements note 2".

In 2007, we narrowed our focus solely to healthcare through the divestments of the Medical Nutrition (effective July 1) and Gerber Business Units (effective September 1).

At the same time, contributions from strategic acquisitions have a significant impact on the Group's results of operations. The remaining stake in Chiron Corporation was acquired in April 2006 to create the new Vaccines and Diagnostics Division, while Sandoz strengthened its position as a world leader in generic pharmaceuticals through the 2005 acquisitions of Hexal AG and Eon Labs, Inc.

As a result of these acquisitions and also through other actions such as the agreement in 2008 providing future rights to majority control of the eye-care company Alcon the Group's results of operations are increasingly affected by charges for the amortization of intangible assets as well as impairment charges and other one-time costs related to the integration of acquisitions.

Novartis continually evaluates potential opportunities for targeted acquisitions or other strategic transactions, including product licensing agreements, that would improve our competitive position and create value for shareholders.

Acquisitions in 2008

Corporate Alcon

On April 7, Novartis announced an agreement with Nestlé S.A. under which we obtained rights to acquire in two steps majority ownership of Alcon Inc. (NYSE: ACL), a Swiss-registered company only listed on the New York Stock Exchange. The potential total value of the two steps is up to approximately $39 billion. The first step was completed on July 7, 2008, when Novartis acquired an initial 24.8% stake in Alcon, representing 74 million shares, from Nestlé for $10.4 billion in cash. Alcon's closing share price was $148.44 on April 4, the last trading day before the signing of this agreement. However, the investment reflects a price of $140.68 per share. The transaction price of $143.18 per share was determined by using Alcon's volume-weighted average share price between January 7, 2008, and April 4, 2008. This price was later reduced by approximately $2.50 per share to account for the dividend paid by Alcon in May 2008. We paid for this stake from internal cash reserves and external short-term financing.

In the optional second step, Novartis has the right to acquire Nestlé's remaining 52% majority stake in Alcon between January 1, 2010, and July 31, 2011, for a fixed price of $181.00 per share, or approximately $28 billion. During this period, Nestlé has the right to require us to buy its remaining stake at a 20.5% premium to Alcon's share price at the time of exercise, but not exceeding $181.00 per share. We have no obligation to purchase the remaining 23% of shares held by Alcon minority shareholders.

The Group has determined that the put and call options represent contracts in a business combination to buy, sell or acquire at a future date, and are therefore exempt from recognition under IAS 39.

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The purchase price allocation of the $10.4 billion paid for the 24.8% stake consisted of the Group's share of Alcon's reported net assets ($1.1 billion), additionally appraised tangible and intangible assets ($5.1 billion) and implicit goodwill ($4.2 billion). Since the July 7 acquisition date the investment has contributed a loss of $11 million to the 2008 consolidated income statement.

As a result of the 37% decline in Alcon's share price at the end of 2008 to $89.19 from the price paid for the initial 24.8% stake, Novartis performed an impairment test on the investment's carrying value.

This test assessed the "value in use" to Novartis of this strategic investment by valuing estimated discounted cash flows and future dividend streams from Alcon against the "fair value less costs to sell" of this stake, as measured by the closing price on December 31, 2008, on the NYSE for the 23% of Alcon's publicly traded shares.

Since the higher of the estimated "value in use" and the "fair value less costs to sell" exceeded the carrying value of $140.68 per share, no impairment charge was recorded. Key assumptions and sensitivity analysis information are provided in "Item 18. Financial Statements note 10".

If only Alcon's year-end closing price had been used for the impairment test, the value of this investment would have been $6.6 billion, or approximately $3.8 billion below the year-end carrying value on the Novartis consolidated balance sheet. If this amount had been used as an impairment charge, the Group's reported net income in 2008 of $8.2 billion would have been reduced by approximately $3.5 billion to $4.7 billion.

Pharmaceuticals Speedel

On July 10, Novartis announced the all-cash purchase of an additional 51.7% stake in Speedel Holding AG (SIX: SPPN) through off-exchange transactions together with plans to buy all remaining shares in the Swiss biopharmaceuticals company in a mandatory public tender offer under the same conditions. Following these actions, and in addition to the previously held 9.5% stake, Novartis now holds more than 99.8% of Speedel's outstanding shares. This process, including the delisting of Speedel's shares on the SIX Swiss Exchange, is expected to be completed in early 2009. The acquisition price for the 90.3% interest not previously held is approximately CHF 939 million (or $888 million) excluding $26 million of cash held by Speedel as of the July acquisition of majority control. Speedel has been fully consolidated as a subsidiary since the July acquisition date of a majority stake. Based on a final purchase price allocation, Speedel's identified net assets were $472 million and produced goodwill of $493 million. As a result of this purchase price allocation, the value of the initial 9.5% stake rose by $38 million, which was recorded in the consolidated statement of recognized income and expense. The consolidation of Speedel resulted in immaterial amounts being included in the Group's 2008 consolidated income and operating cash flow statements.

Pharmaceuticals Protez

On June 4, Novartis agreed to acquire Protez Pharmaceuticals, a privately held US biopharmaceuticals company, and gaining access to PTZ601, a broad-spectrum antibiotic in Phase II development against potentially fatal drug-resistant bacterial infections. Novartis paid $102 million in cash to acquire 100% of Protez, whose owners are eligible for additional payments of up to $300 million contingent upon the future success of PTZ601. Protez has been consolidated since the transaction completion date of July 17. Based on the purchase price allocation, identified net assets from Protez amounted to $72 million and produced goodwill of $30 million. The consolidation of Protez has resulted in immaterial amounts being included in the Group's 2008 consolidated income and operating cash flow statements.

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Pharmaceuticals Nektar pulmonary business

On October 21, Novartis agreed to acquire Nektar Therapeutics Inc.'s pulmonary business unit for $115 million in cash. In this transaction, which was completed on December 31, 2008, Novartis acquired research, development and manufacturing assets of Nektar's pulmonary business unit, including tangible assets as well as intellectual property, intangible assets and related expertise. The full purchase price has been allocated to the net assets acquired with no residual goodwill.

Other Significant Transactions in 2008

Corporate Issuance of Swiss franc bonds

On June 26, Novartis issued two Swiss franc bonds totaling CHF 1.5 billion (approximately $1.4 billion) in the Swiss capital market, with each listed on the SIX Swiss Exchange. One was a 3.5% four-year bond for a total of CHF 700 million issued by Novartis Securities Investment Ltd. and guaranteed by Novartis AG. The other was a 3.625% seven-year bond of CHF 800 million issued by Novartis AG.

Divestments/Discontinued Operations in 2007

Consumer Health Gerber Business Unit

On September 1, Novartis completed the divestment of the Gerber infant products Business Unit for approximately $5.5 billion to Nestlé S.A. resulting in a pre-tax divestment gain of approximately $4.0 billion and an after-tax gain of $3.6 billion.

Consumer Health Medical Nutrition Business Unit

On July 1, Novartis completed the divestment of the remainder of the Medical Nutrition Business Unit for approximately $2.5 billion to Nestlé S.A. resulting in a pre-tax divestment gain of $1.8 billion and an after-tax gain of $1.6 billion.

Gerber and Medical Nutrition are reported as discontinued operations in all periods in the Group's consolidated financial statements. These businesses in total had 2007 net sales of $1.7 billion and operating income of $311 million before their respective divestment.

Other Significant Transactions in 2007

Vaccines and Diagnostics Intercell

On September 28, Novartis entered into a strategic alliance with Intercell AG, an Austrian biotechnology company focused on vaccines development. In accordance with the agreement, Novartis paid $383 million (EUR 270 million), and also recorded $207 million (EUR 146 million) of intangible assets and acquired an additional 4.8 million shares for $176 million (EUR 124 million) that increased the Novartis holding in Intercell to 15.9%. The equity investment is accounted for as an available-for-sale marketable security within the financial assets of the division.

Pharmaceuticals Betaseron®

On September 14, Novartis and Bayer Schering Pharma AG received regulatory approval to complete an agreement related to various rights for the multiple sclerosis treatment Betaseron® under an earlier agreement between Schering and Chiron Corporation transferred to Novartis in April 2006. Under the new agreement, Novartis received a one-time payment of $200 million, principally for manufacturing facilities transferred to Bayer Schering, as well as receiving rights to market a Novartis-branded version of Betaseron® called *Extavia* starting in 2009 in the EU and later in the US following anticipated approval. As a result of the clarification of the intangible product rights, a reassessment was made of the related

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assets from the Chiron acquisition as of April 20, 2006. This resulted in an increase of $235 million in identified net assets in 2007 relating to the Chiron 2006 acquisition.

Acquisitions in 2006

Vaccines and Diagnostics Chiron

On April 20, Novartis completed the acquisition of the remaining 56% of the shares of Chiron Corporation that we did not already own for approximately $5.7 billion. For the period from January 1, 2006 until completion of the acquisition, the 44% minority interest in Chiron held by us had been accounted for using the equity method. For the period after completion of the acquisition, Chiron has been fully consolidated with its identifiable assets and liabilities being revalued to their fair value at the date of acquisition. Following the acquisition, Chiron's vaccines and diagnostic activities are reported as a separate Division, called Vaccines and Diagnostics, and its pharmaceuticals activities are consolidated into the Pharmaceuticals Division's results.

Pharmaceuticals NeuTec

In 2006, we acquired 100% of NeuTec Pharma plc, a biopharmaceuticals company specializing in hospital anti-infectives, for $606 million. We have fully consolidated NeuTec's financial results, which have not included any sales, in our financial statements since July 14, 2006.

Divestments/Discontinued Operations in 2006

Consumer Health Medical Nutrition Business Unit

During 2006, Novartis announced plans to divest the components of our Medical Nutrition Business Unit, which was part of our Consumer Health Division. This Business Unit is disclosed as discontinued operations in all periods presented in our consolidated financial statements.

On February 17, we completed the sale of Nutrition & Santé for $211 million to ABN AMRO Capital France, resulting in a pre-tax divestment gain of $129 million.

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EFFECTS OF CURRENCY FLUCTUATIONS

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

The following provides an overview of net sales and expenses from continuing operations for 2008 and 2007 for currencies most important to the Group:

Currency	2008 in %	2007 in %	2006 in %
US dollar (USD)			
Net sales	34	39	43
Operating expenses	31	36	38
Euro (EUR)			
Net sales	32	30	27
Operating expenses	28	28	25
Swiss franc (CHF)			
Net sales	2	2	2
Operating expenses	16	14	16
Japanese yen (JPY)			
Net sales	7	6	7
Operating expenses	5	5	5
Other currencies			
Net sales	25	23	21
Operating expenses	20	17	16

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

For purposes of our consolidated balance sheets, we translate assets and liabilities denominated in other currencies into US dollars at the prevailing market exchange rates as of the relevant balance sheet date. As a result, even if the amounts or values of these items remain unchanged in the respective local currency, changes in exchange rates have an impact on the amounts or values of these items in our consolidated financial statements. For purposes of the Group's consolidated income statements, revenue and expense items in local currencies are translated into US dollars at average exchange rates prevailing during the relevant period.

We seek to manage currency exposure by engaging in hedging transactions where management deems appropriate. For 2008, we entered into various contracts that change in value with movements in foreign exchange rates in order to preserve the value of assets, commitments and expected transactions. We also use forward contracts and foreign currency options to hedge expected net revenues in foreign currencies. For more information on how these transactions affect our consolidated financial statements and on how foreign exchange rate exposure is managed, see "Item 18. Financial Statements note 1", " note 5" and " note 15".

The average value of the US dollar against other currencies important for Novartis deteriorated significantly in 2008. The following table sets forth the foreign exchange rates of the US dollar against the

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Swiss franc, euro and Japanese yen, respectively, used for foreign currency translation when preparing the Group's consolidated financial statements:

	2008		2007		2006	
$ per unit	Average for year	Year end	Average for year	Year end	Average for year	Year end
EUR	1.470	1.411	1.371	1.465	1.256	1.317
CHF	0.925	0.948	0.834	0.881	0.798	0.819
JPY (100)	0.970	1.107	0.850	0.884	0.860	0.841

Currency translation impact on key figures Continuing Operations

	Local Currencies Change in % 2008	Local Currencies Change in % 2007	$ Change in % 2008	$ Change in % 2007
Net sales	5	6	9	11
Operating income	20	(14)	32	(11)
Net income	13	(7)	25	(4)

For additional information on the effects of currency fluctuations see "Item 11. Quantitative and Qualitative Disclosures about Non-Product-Related Market Risk."

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our principal accounting policies are set out in "Item 18. Financial Statements note 1" and are prepared in accordance with IFRS as issued by the IASB. As a result of uncertainties inherent in our business activities, we need to make certain estimates and assumptions that require we make difficult, subjective and complex judgments. Because of uncertainties inherent in such judgments, actual outcomes and results may differ from our assumptions and estimates. Application of the following accounting policies requires certain assumptions and estimates that have the potential for the most significant impact on our consolidated financial statements.

Revenue

We recognize product sales when there is persuasive evidence that a sales arrangement exists, title and risk and rewards for the products are transferred to the customer, the price is fixed and determinable, and collectability is reasonably assured. At the time of the sale, we also record estimates for a variety of sales deductions, including rebates, discounts and incentives, and product returns. Sales deductions are reported as a reduction of revenue.

Deductions from Revenues

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

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The following summarizes the nature of some of these deductions and how the deduction is estimated. The US market has the most complex arrangements related to revenue deductions. Specific reference is therefore made to the US market and where applicable to the Pharmaceuticals Division's primary US operating unit, Novartis Pharmaceuticals Corporation (NPC). However, in a number of countries outside the US, including major European countries, we provide rebates to government entities. These rebates are often legislatively mandated.

The US Medicaid program is administered by State governments 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, Novartis subsidiaries have signed agreements to provide a rebate on drugs paid for by a State. Calculating the rebates to be paid involves interpreting relevant regulation, which are subject to challenge or change in interpretive guidance by government authorities. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, product price increases, the mix of contracts and specific terms in the individual State agreements. These provisions are adjusted based upon established processes and experiences from re-filing data with individual States.

On January 1, 2006, an additional prescription drug benefit was added to the US Medicare program, which funds healthcare benefits to individuals over the age of 65. Individuals who previously had dual Medicaid/Medicare drug benefit eligibility had their Medicaid prescription drug coverage replaced on January 1, 2006, by the new Medicare Part D coverage. This benefit is provided through private prescription drug plans, and this change led to a significant shift of plan participants between the two programs in which some of our US subsidiaries participate. Provisions for estimating Medicare Part D rebates are calculated based on the terms of individual plan agreements, product sales and population growth, product, price increases and the mix of contracts.

Any rebate adjustments may involve revisions of provisions for several periods since Medicaid and Medicare rebate claims are typically submitted to Novartis up to six months after the products are dispensed to patients.

Our US subsidiaries participate in industry and government sponsored programs designed to offer savings on prescription drugs to eligible patients. These savings depend on a patient's current drug coverage and personal income level. Provisions for obligations resulting from these programs are based on historical experience, trend analysis and current program terms.

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

We offer rebates to key managed healthcare plans, group purchasing organizations and other direct and indirect customers to sustain and increase the market share of our products. These rebate programs provide customers a rebate after they attain certain performance parameters relating to product purchases, formulary status or pre-established market share milestones relative to competitors. Since rebates are contractually agreed upon, rebates are estimated based on the terms of individual agreements, historical experience, expected mix of reimbursement programs and

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projected product growth rates. We adjust provisions related to customer rebates periodically to reflect actual experience.

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

When we sell a product that the customer has a right to return, we record a provision for estimated sales returns, based on the historical rate of returns. Other factors are also considered, such as product recalls, expected marketplace changes and, in the US, the entry of generic products. In 2008, sales returns amounted to approximately 1% of gross product sales. In the Vaccines and Diagnostics Division, where no Novartis specific historical return rate experience is available, sales are only recorded based on evidence of product consumption.

We adjust the shipping patterns of our pharmaceutical products to maintain customer inventories that are consistent with underlying patient demand. In the US we monitor inventory levels at wholesalers based on gross sales volume and prescription volumes obtained from third party data and information received from key wholesalers. Based on this information, we estimate that inventories of NPC's pharmaceutical products on hand at wholesalers and other distribution channels in the US were approximately one month at December 31, 2008.

NPC has entered into fee-for-service agreements with certain US pharmaceutical wholesalers. These agreements cover items such as product returns, timing of payment, processing of chargebacks, provision of inventory data and the quantity of inventory held by the wholesaler. These agreements provide a financial disincentive for wholesalers to purchase product quantities in excess of what is necessary to meet current demand.

We offer cash discounts to customers in the US and other countries to encourage prompt payment. Cash discounts, which are typically 2% of gross sales in the US, are accrued at the time of invoicing and deducted from revenue.

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

Other sales discounts, such as consumer coupons and discount cards, are also offered in some markets. These discounts are recorded at the time of sale, or when the coupon is issued, and are estimated utilizing historical experience and the specific terms for each program.

Discounts, rebates or other deductions shown on invoices to customers are generally deducted directly from gross sales without recording them in the revenue deduction provision.

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The following tables show the worldwide extent of our revenue deductions, related payment experiences and provisions:

Provision for revenue deductions

2008	Provisions offset against gross trade accounts receivable at January 1, 2008	Provisions at January 1, 2008	Effect of currency translation	Payments/ utilizations	Income Statement charge: Adjustments of prior years	Income Statement charge: Current year	Provisions offset against gross trade accounts receivable at December 31, 2008	Provisions at December 31, 2008
	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)
US Medicaid, Medicare and State program rebates & credits including prescription drug saving card rebates		490		(754)	(117)	762		381
US managed healthcare rebates		197		(423)	2	493		269
Non-US healthcare plans & programs rebates		174	(12)	(281)	(16)	450		315
Chargebacks (including hospitals)	296		(14)	(1,934)		1,936	(218)	66
Direct customer discounts, cash discounts & other rebates	336	159	(5)	(1,298)	(3)	1,223	(311)	101
Sales returns & other deductions		492	(24)	(496)	(12)	573		533
Total	**632**	**1,512**	**(55)**	**(5,186)**	**(146)**	**5,437**	**(529)**	**1,665**

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2007	Provisions offset against gross trade accounts receivable at January 1, 2007	Provisions at January 1, 2007	Effect of currency translation and from discontinued operations	Payments/ utilizations	Income Statement charge: Adjustments of prior years	Income Statement charge: Current year	Provisions offset against gross trade accounts receivable at December 31, 2007	Provisions at December 31, 2007
	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)
US Medicaid, Medicare and State program rebates & credits including prescription drug saving card rebates		538		(780)	(91)	823		490
US managed healthcare rebates		235		(477)	(21)	460		197
Non-US healthcare plans & programs rebates		76	14	(133)	5	212		174
Chargebacks (including hospitals)	329		(16)	(2,319)	(5)	2,307	(296)	
Direct customer discounts, cash discounts & other rebates	273	108	4	(1,243)	(23)	1,376	(336)	159
Sales returns & other deductions		471	(30)	(515)	(20)	586		492
Total	**602**	**1,428**	**(28)**	**(5,467)**	**(155)**	**5,764**	**(632)**	**1,512**

2006	Provisions offset against gross trade accounts receivable at January 1, 2006	Provisions at January 1, 2006	Effect of currency translation and from discontinued operations	Payments/ utilizations	Income Statement charge: Adjustments of prior years	Income Statement charge: Current year	Provisions offset against gross trade accounts receivable at December 31, 2006	Provisions at December 31, 2006
	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)	($ millions)
US Medicaid, Medicare and State program rebates & credits including prescription drug saving card rebates		497		(643)	(35)	719		538
US managed healthcare rebates		256		(457)	(5)	441		235
Non-US healthcare plans & programs rebates		35	6	(108)	2	141		76
Chargebacks (including hospitals)	379		7	(2,340)	(3)	2,286	(329)	
Direct customer discounts, cash discounts & other rebates	256	66	89	(989)	(22)	981	(273)	108
Sales returns & other deductions		408	43	(579)	(13)	612		471

Total	**635**	**1,262**	**145**	**(5,116)**	**(76)**	**5,180**	**(602)**	**1,428**

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Gross to Net sales reconciliation

2008	Income Statement charge Charged through revenue deduction provisions 2008 ($ millions)	Income Statement charge Charged directly without being recorded in revenue deduction provisions 2008 ($ millions)	Total 2008 ($ millions)	In % of 2008 gross sales
Group gross sales subject to deductions			**49,972**	**100.0**
US Medicaid, Medicare and State program rebates and credits, including prescriptions drug savings card rebates	(645)	(96)	(741)	(1.5)
US managed healthcare rebates	(494)		(494)	(1.0)
Non-US healthcare plans and program rebates	(434)	(105)	(539)	(1.1)
Chargebacks (including hospitals)	(1,936)	(146)	(2,082)	(4.2)
Direct customer discounts, cash discounts and other rebates	(1,220)	(2,328)	(3,548)	(7.1)
Sales returns and other deductions	(562)	(547)	(1,109)	(2.2)
Total gross to net sales adjustments	**(5,291)**	**(3,222)**	**(8,513)**	**(17.1)**
Group net sales			**41,459**	**82.9**

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2007	Income Statement charge Charged through revenue deduction provisions 2007 ($ millions)	Charged directly without being recorded in revenue deduction provisions 2007 ($ millions)	Total 2007 ($ millions)	In % of 2007 gross sales
Gross sales subject to deductions from continuing operations			**46,426**	**100.0**
Gross sales subject to deductions from discontinued operations			1,985	
Group gross sales subject to deductions			**48,411**	
US Medicaid, Medicare and State program rebates and credits, including prescriptions drug savings card rebates	(731)	(57)	(788)	(1.7)
US managed healthcare rebates	(439)		(439)	(0.9)
Non-US healthcare plans and program rebates	(217)	(113)	(330)	(0.7)
Chargebacks (including hospitals)	(2,247)	(73)	(2,320)	(5.0)
Direct customer discounts, cash discounts and other rebates	(1,330)	(1,988)	(3,318)	(7.1)
Sales returns and other deductions	(561)	(598)	(1,159)	(2.5)
Total gross to net sales adjustments from continuing operations	**(5,525)**	**(2,829)**	**(8,354)**	**(17.9)**
Net sales from continuing operations			**38,072**	**82.1**