NOVARTIS AG Form 20-F January 31, 2007

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As filed with the Securities and Exchange Commission on January 31, 2007

# 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
- ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2006

OR

- $_{
  m O}$  TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
- 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)

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

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

Name of each exchange on which registered 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:

#### 2,348,231,459 shares

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

#### Yes ý No o

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

#### Yes o No ý

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

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

#### Yes ý No o

Indicate by check mark whether the registrant 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 financial statement item the registrant has elected to follow.

#### Item 17 o Item 18 ý

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, 2006. In this Form 20-F, references to "US dollars", "USD" or "\$" are to the lawful currency of the United States of America; and references to "CHF" are to Swiss francs.

In this Form 20-F, references to the "United States" or to "US" are to the United States of America, references to "Europe" are to all European countries (including Turkey, Russia and the Ukraine), references to the European Union ("EU") are to the European Union and its 25 member states and references to "Americas" are to North, Central (including the Caribbean) and South America, unless the context otherwise requires; references to "Novartis" or the "Group" are to Novartis AG and its consolidated subsidiaries; 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 which 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.

We furnish to registered holders of Novartis AG shares ("shares") annual reports that include a description of operations and annual audited consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRS"). IFRS differs in certain significant respects from US Generally Accepted Accounting Principles ("US GAAP"). See "Item 18. Financial Statements note 33" for a description of the significant differences between IFRS and US GAAP. The financial statements included in the annual reports are examined and reported upon by our independent auditors. We make available to our shareholders, on our web page, quarterly interim press releases that include unaudited interim consolidated financial information prepared in conformity with IFRS with a reconciliation to US GAAP.

#### FORWARD LOOKING STATEMENTS

This Form 20-F contains certain "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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 such products, potential future expenditures or liabilities, or by discussions of strategy, plans or intentions. Such forward-looking statements 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 of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Novartis or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; uncertainties regarding necessary levels of expenditures in the future; and uncertainties regarding judicial or other investigatory proceedings. Some of these factors are discussed in more detail herein, including under "Item 3. Key Information-3.D. Risk factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects." Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Form 20-F as anticipated, believed, estimated or expected. We provide the information in this 20-F as of the date of its filing. We do not intend, and do not assume any obligation, to update any information or forward looking statements set out in this Form 20-F.

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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. Our consolidated financial statements for the years ended December 31, 2006, 2005 and 2004 are included elsewhere in this Form 20-F.

In order to assist our investors and analysts in their understanding of our results by having comparable information, 2004 pro forma consolidated income and cash flow statements are provided that include additional adjustments compared to the audited 2004 consolidated income and cash flow statements. We present pro forma financial statements because we adopted a number of new International Financial Reporting Standards from January 1, 2005 and not all of the new standards required retrospective application. In addition, the results of our Medical Nutrition Business Unit are shown as discontinuing operations for all periods, following our decision in 2006 to divest this business. See "Item 5. Operating and Financial Review and Prospects 5.A Operating Results Factors Affecting Comparability of Year-on-Year Results of Operations" for a 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 such notes.

The consolidated financial statements used to create the selected consolidated financial data set forth below were prepared in accordance with IFRS. IFRS differs in certain respects from US GAAP. For a discussion of the significant differences between IFRS and US GAAP, see "Item 18. Financial Statements" note 33."

2004<sup>(1)</sup> Pro

### Year Ended December 31,

	2006	2005	Forma	2004(2)	2003(2)	2002(2)
	(\$ millions, except per share information)					
INCOME STATEMENT DATA						
Amounts in accordance with IFRS:						
Net sales from continuing operations	36,031	31,005	27,126	27,126	24,049	19,957
Operating income from continuing						
operations	7,949	6,802	6,243	6,117	5,553	4,884
Income/(loss) from associated companies	264	193	177	68	(279)	(18)
Financial income	354	461	488	486	621	807
Interest expense	(266)	(294)	(261)	(261)	(243)	(214)
Income before taxes from continuing						
operations	8,301	7,162	6,647	6,410	5,652	5,459
Taxes	(1,282)	(1,090)	(1,072)	(1,045)	(919)	(917)
Net income from continuing operations	7,019	6,072	5,575	5,365	4,733	4,542
Net income from discontinuing operations	183	69	26	15	54	136
Net meone from discontinuing operations	103		20	13	34	130
Group net income	7,202	6,141	5,601	5,380	4,787	4,678
Attributable to Shareholders of Novartis AG	7,175	6,130	5,586	5,365	4,743	4,664
Minority interests	27	11	15	15	44	14
,						
Operating income from discontinuing						
operations	225	103	35	46	82	144
Basic earnings per share in \$:						
Continuing operations earnings per share in \$	2.98	2.60	2.36	2.27	1.97	1.87
Discontinuing operations earnings per share						
in \$	0.08	0.03	0.01	0.01	0.02	0.06
Total earnings per share in \$	3.06	2.63	2.37	2.28	1.99	1.93
Diluted earnings per share in \$:						
Continuing operations diluted earnings per						
share in \$	2.96	2.59	2.35	2.26	1.95	1.84
Discontinuing operations diluted earnings per						
share in \$	0.08	0.03	0.01	0.01	0.02	0.05
Total diluted earnings per share in \$	3.04	2.62	2.36	2.27	1.97	1.89
Cash dividends <sup>(3)</sup>	2,049	2,107	1,896	1,896	1,659	1,311
Cash dividends per share in CHF <sup>(4)</sup>	1.35	1.15	1.05	1.05	1.00	0.95
Operating income from continuing operations						
per share in \$:						
Basic earnings per share in \$	3.39	2.92	2.65	2.60	2.33	2.02
Diluted earnings per share in \$	3.37	2.90	2.64	2.58	2.30	1.97

Data is pro forma. See "Item 5.A Operating Results."

(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, 2003 and 2002 is therefore not comparable with 2006, 2005 and 2004 pro forma.

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

(4)

Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2006 will be proposed to the Annual General Meeting on March 6, 2007 for approval.

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# Year Ended December 31,

	2006	2005	2004	2003	2002
		(\$ millions,	except per sh	are data)	
BALANCE SHEET DATA					
Amounts in accordance with IFRS:					
Cash, cash equivalents and current marketable					
securities	7,955	10,933	13,892	12,621	12,050
Inventories	4,498	3,725	3,558	3,346	2,963
Other current assets	8,215	6,785	6,470	5,677	5,316
Non-current assets	46,604	36,289	28,568	26,734	24,012
Assets related to discontinuing operations	736				
Total assets	68,008	57,732	52,488	48,378	44,341
Trade accounts payable	2,487	1,961	2,020	1,665	1,266
Other current liabilities	13,540	13,367	9,829	8,254	7,560
Non-current liabilities	10,480	9,240	9,324	9,416	8,064
Liabilities related to discontinuing operations	207	7,240	7,324	7,410	0,004
Fotal liabilities	26,714	24,568	21,173	19,335	16,890
Total equity available to Novartis AG shareholders	41,111	32,990	31,177	28,953	27,385
Minority interests	183	174	138	90	66
Fotal equity	41,294	33,164	31,315	29,043	27,451
otal liabilities and equity	68,008	57,732	52,488	48,378	44,341
Net assets	41,294	33,164	31,315	29,043	27,451
Outstanding share capital	850	848	849	862	863
Amounts in accordance with US GAAP:					
ncome statement data					
let income from continuing operations	5,150	5,121	4,778	3,570	3,680
let income discontinuing operations	114	69	15	54	136
roup net income	5,264	5,190	4,793	3,624	3,816
ontinuing operations earnings per share in \$	2.19	2.19	2.02	1.50	1.52
Discontinuing operations earnings per share in \$	0.05	0.03	0.01	0.02	0.06
	2.24	2.22	2.03	1.52	1.58
ontinuing operations diluted earnings per share					
Continuing operations diluted earnings per share	2.18	2.19	2.01	1.48	1.49
Continuing operations diluted earnings per share  n \$ Discontinuing operations diluted earnings per share	2.18				
Continuing operations diluted earnings per share  1 \$ Discontinuing operations diluted earnings per share 1 \$	2.18 0.05	0.03	0.01	0.02	0.05
Continuing operations diluted earnings per share  n \$ Discontinuing operations diluted earnings per share n \$	2.18				
Continuing operations diluted earnings per share  n \$ Discontinuing operations diluted earnings per share n \$ Fotal diluted earnings per share in \$ Balance sheet data	2.18 0.05 2.23	0.03 2.22	0.01 2.02	0.02 1.50	0.05 1.54
Total earnings per share in \$ Continuing operations diluted earnings per share in \$ Discontinuing operations diluted earnings per share in \$ Total diluted earnings per share in \$  Balance sheet data Total equity Total assets	2.18 0.05	0.03	0.01	0.02	0.05

#### 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	Total Dividend per ADS	
		(CHF)	(\$)	
2002	March 2003	0.95	0.68	
2003	February 2004	1.00	0.80	
2004	March 2005	1.05	0.93	
2005	February 2006	1.15	087	
$2006^{(1)(2)}$	March 2007	1.35	1.11	
2002 2003 2004 2005	March 2003 February 2004 March 2005 February 2006	(CHF)  0.95 1.00 1.05 1.15	(\$) 0.68 0.80 0.93 087	

<sup>(1)</sup> If the Swiss franc amount for 2007 is translated into US dollars at the rate of \$0.82 to the Swiss franc, the Total Dividend per share and Total Dividend per ADS in US dollars would be \$1.11. 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.

#### **Exchange Rates**

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Reuters Market System. The exchange rate in effect on January 25, 2007, as found on Reuters Market System, was CHF 1.00 = \$0.80.

Year ended December 31,	Period End	Average <sup>(1)</sup>	Low	High
2002	0.71	0.65	0.50	0.50
2002	0.71	0.65	0.58	0.72
2003	0.80	0.75	0.70	0.81
2004	0.88	0.81	0.76	0.88
2005	0.76	0.80	0.75	0.88
2006	0.82	0.80	0.76	0.84
Month end, August 2006			0.80	0.82
September 2006			0.79	0.81
October 2006			0.79	0.80
November 2006			0.80	0.83
December 2006			0.82	0.84
January 2007 <sup>(2)</sup>			0.80	0.82

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

#### 3.B Capitalization and Indebtedness

Not applicable.

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

Not applicable.

<sup>(2)</sup> Dividend to be proposed at the Annual General Meeting on March 6, 2007 and paid in March 2007.

<sup>(2)</sup> The high and low US dollar/Swiss franc exchange rate is current as of January 25, 2007.

#### 3.D Risk Factors

Our business faces significant risks and uncertainties. You should carefully consider all of the information set forth in this annual report on Form 20-F and in our other filings with the SEC before deciding to invest in any Novartis securities, including the following risk factors faced by us and our industry. Our business, 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 which we presently deem immaterial.

#### **Risks Facing Our Business**

#### Our business is significantly affected by ongoing pricing pressures.

Our business and the healthcare industry in general are significantly affected by ongoing pricing pressures. These pricing pressures include government-imposed industry-wide price reductions, mandatory reference prices, an increase in parallel imports, the shifting of the payment burden to patients through higher co-payments, 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 governments, healthcare providers, insurance companies and other stakeholders step up initiatives to reduce the overall cost of healthcare to patients, restrict the prescribing of new medicines, increase the use of generics and impose overall price cuts. These initiatives do not only affect the results of our Pharmaceuticals Division, but also have an increasing impact on the prices which we are able to charge for the generic drugs marketed by our Sandoz Division. This is particularly true in Germany, our second largest market for generic products, where various measures were introduced to require generic manufacturers to lower their prices. Similar effects are also being felt on Sandoz's business in other markets, particularly in Europe. We expect that these and other challenges will continue to put pressure on our revenues, and therefore could have an adverse effect on our business, financial condition or results of operations.

For more information on the pricing controls and on our challenging business environment see "Item 4.B Business Overview Pharmaceuticals Price Controls" and "Item 5.A Operating Results Factors affecting results of operations Challenging Business Environment and Ongoing Pricing Pressures".

#### Our Pharmaceuticals Division faces intense competition from lower-cost generic products.

Our Pharmaceuticals Division faces increasing competition from lower-cost generic products. Our Pharmaceuticals Division's products are generally protected by patent rights which are expected to provide us with exclusive marketing rights in various countries. However, those patent rights are of varying strengths and durations. Loss of market exclusivity and the introduction of a generic version of the same or a similar medicine typically results in a significant and sharp reduction in net sales for the relevant product, given that generic manufacturers typically offer their versions of the same medicine at sharply lower prices.

In 2007, there is a significant risk that generic competition will emerge for our Top 20 product *Trileptal* and that US generic competition will emerge for our Top 20 product *Lamisil*, which already faces generic competition outside the US. *Lamisil*'s US patent will expire in June 2007. In 2006, *Lamisil* accounted for \$574 million in annual sales in the US, or 1.6% of our net sales from continuing operations (3.9% of the sales in the US). Similarly, patent protection for *Trileptal*'s active ingredient has expired in the US and other major countries. In 2006, *Trileptal* accounted for \$549 million in sales in the US, or 1.5% of our net sales from continuing operations (3.8% of our sales in the US).

In addition to *Lamisil*, three other products that are still among our Top 20 products have already encountered generic competition in some markets: *Neoral, Sandostatin SC* and *Voltaren*. As a result, revenue from these products has declined, and may decline significantly further in the future. A number of our other top-selling products, including the anti-hypertension drugs *Diovan* and *Lotrel* as well as the

oncology drugs *Gleevec/Glivec* and *Zometa*, could also potentially face generic competition in the coming five to ten years in various markets, particularly the US and Europe.

#### Competition in the healthcare industry is generally becoming more intense.

Competition in the healthcare industry generally continues to intensify. The time between the launch of innovative "first-in-class" treatments and "me-too" or generic versions has shortened significantly in recent years, which is putting increasing pressure on our Pharmaceuticals Division to maximize revenue from a new product quickly following its launch, in order to be able to recover its significant research and development costs. As a result of increasing competition from generic companies, certain research-based pharmaceutical companies have started to sell their products directly to the generic market upon expiration of their patents by forming strategic alliances with generic pharmaceutical companies. This allows them to undercut the revenues and profitability of generic manufacturers, including our Sandoz Division. At the same time, competition among generics manufacturers also continues to intensify as the entire healthcare industry adjusts to increased pressures by governments and other stakeholders to contain healthcare costs. Finally, the generic industry is rapidly consolidating and has witnessed the emergence of large, global market players that compete vigorously for market share. We expect all of these trends to continue, which could have a material adverse effect on our business, financial condition and results of operations.

#### Our Sandoz Division may face patent infringement lawsuits by research-based pharmaceutical companies.

From time to time, our Sandoz Division may seek approval to market a generic version of a product before the expiration of patents claimed by others for the relevant 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. 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. This could have a material adverse effect on our business, financial condition or results of operations.

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

Our ability to continue to grow our business and to replace any lost sales due to the loss of exclusivity for our products due to patent expiration depends upon the ability of our research and development activities to identify and develop high-potential breakthrough products and to bring them to market. 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 and there can be no guarantee that our research and development activities will produce a sufficient number of commercially viable new products, in spite of these significant investments.

In the pharmaceuticals business, the research and development process can take up to 12 years, or even longer, from discovery to commercial product launch. New products do not only need to undergo intensive pre-clinical and clinical testing, but also pass a highly complex, lengthy and expensive approval process. During each stage of the process, there is a substantial risk that we will encounter serious obstacles or will not achieve our goals and accordingly we may abandon a product in which we have invested substantial amounts of time and money. There also appears to be a renewed focus on product safety by regulatory authorities following widely publicized product recalls such as Merck & Co.'s recall of its pain medicine Vioxx®. As a result, regulatory authorities may be more cautious in approving new products or even reassess the safety and efficacy of our existing products. If we are unable to maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient to cover our substantial research and development costs and to replace sales that are lost as older products approach the end of their commercial life cycles or are displaced by competing