# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 6-K

### **REPORT OF FOREIGN PRIVATE ISSUER**

# PURSUANT TO RULE 13a-16 or 15d-16 OF

### THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated January 27, 2011

(Commission File No. 1-15024)

# **Novartis AG**

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

**Form 20-F:** x Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o No: x

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o No: x

Novartis International AG Novartis Global Communications CH-4002 Basel Switzerland http://www.novartis.com

- Investor Relations Release -

Innovation drives Novartis to double-digit growth for 2010

• Novartis achieved strong financial results in 2010

• Net sales up 14% (+14% in constant currencies, or cc) to USD 50.6 billion

• **Operating income up 15% (+17% cc)**; core operating income up 22% (+24% cc); core operating income margin up by 1.9 percentage points to 27.7% of net sales

- EPS up 16% to USD 4.28; core EPS up 14% to USD 5.15
- Free cash flow before dividends up 31% to USD 12.3 billion
- 14th consecutive dividend increase; CHF 2.20 per share proposed for 2010
- Solid sales growth in fourth quarter, operating income impacted by one-offs and A(H1N1) pandemic flu vaccine sales in the prior year
- Net sales up 10% (+11% cc) to USD 14.2 billion
- Operating income declined 6% (-3% cc) to USD 2.5 billion; core operating income decreased 1% (+2% cc) to USD 3.2 billion

• EPS down 6% (-2% cc) to USD 0.95

### Pipeline and recently launched products deliver sustained growth momentum

• Continued rejuvenation of Group s portfolio with recently launched products contributing 21% of net sales (USD 10.4 billion) in 2010

• Industry leading pharmaceutical pipeline with 16 major submissions in 2010 in the US, EU and Japan, including, in the fourth quarter, **ACZ885** in gouty arthritis (EU), *Lucentis* in retinal vein occlusion (EU), **SOM230** in Cushing s disease (EU), and *Afinitor* in advanced neuroendocrine tumors (EU, US); in addition, we filed our meningococcal B vaccine *Bexsero* (EU)

• 13 major approvals gained in Pharmaceuticals in 2010 in the US, EU and Japan, including fourth quarter approvals for *Tasigna* in first-line chronic myeloid leukemia (EU, Switzerland, Japan), for *Lucentis* in diabetic macular edema (EU), and for *Afinitor* in subependymal giant cell astrocytomas associated with tuberous sclerosis (US)

### **Key figures**

	FY 2010	FY 2009	% chai	nge	Q4 2010	Q4 2009	% cha	nge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	50 624	44 267	14	14	14 199	12 926	10	11
Operating income	11 526	9 982	15	17	2 467	2 637	-6	-3
Net income	9 969	8 454	18	20	2 265	2 323	-2	2
EPS (USD)	4.28	3.70	16	17	0.95	1.01	-6	-2
Free cash flow (before								
dividends)	12 346	9 446	31		4 180	3 349	25	
<u>Core(1)</u>								
Operating income	14 006	11 437	22	24	3 166	3 204	-1	2
Net income	12 029	10 267	17	18	2 803	2 892	-3	0
EPS (USD)	5.15	4.50	14	15	1.14	1.26	-10	-6

Basel, January 27, 2011 Commenting on the results, Joseph Jimenez, CEO of Novartis, said:

Novartis achieved excellent results in 2010 as all divisions contributed to above-market growth. I am proud that Novartis continues to lead the industry in innovation, with 13 key product approvals and 16 major filings in Pharmaceuticals in 2010, including our breakthrough multiple sclerosis therapy, Gilenya, which has been launched in the US. We also filed Bexsero, our meningococcal B vaccine, in the EU. In addition, our agreed 100% merger with Alcon, which should complete in the first half of 2011 following shareholder approval, will give us an important new growth pillar and the opportunity to meet some of the most urgent eye care needs of the global aging population.

### **GROUP REVIEW**

#### Full year

Net sales rose 14% (+14% cc) to USD 50.6 billion driven by strong growth in all businesses, including USD 2.4 billion from the consolidation of Alcon, Inc. (Alcon). Recently launched products provided USD 10.4 billion of net sales in the 2010 period, representing 21% of net sales compared to 16% in the 2009 period (excluding Alcon). Pharmaceuticals sales expanded 7% (+6% cc) to USD 30.6 billion driven by 8 percentage points of volume expansion. Recently launched products contributed 21% of Pharmaceuticals sales, up from 16% in 2009. Sandoz achieved double-digit sales growth in 2010 (USD 8.5 billion, +14%, +15% cc) supported by strong growth in US retail generics, biosimilars (+46% cc) and emerging markets such as Middle East, Turkey and Africa (+22% cc). Vaccines and Diagnostics grew to USD 2.9 billion (+25% cc), including USD 1.3 billion of A(H1N1) pandemic flu vaccines. Excluding A(H1N1) pandemic flu vaccines, the business grew 16%. Consumer Health grew 7% (+6% cc) to USD 6.2 billion, with all three business units delivering solid growth in their respective markets.

Operating income rose 15% (+17% cc) to USD 11.5 billion on the volume-driven sales expansion. Unfavorable currency movements negatively impacted operating income by two percentage points. Operating income margin improved 0.3 percentage points to 22.8% of net sales. One-off items arising in the year totaled a net USD 1.3 billion, comprising: impairments (USD 1.0 billion), legal settlements (USD 240 million), restructuring costs (USD 198 million), and Alcon-related costs (USD 596 million), partially offset by divestment and pension curtailment gains (USD 690 million).

Core operating income rose 22% (+24% cc) to USD 14 billion; the core operating income margin rose 1.9 percentage points to 27.7% of net sales. Included in the core operating margin improvement of 1.9 percentage points were a benefit from Alcon of 0.4 percentage points and higher A(H1N1) pandemic flu vaccine sales of 0.5 percentage points, resulting in the increase in the underlying margin of 1.0 percentage points.

Net income advanced 18% (+20% cc) to USD 10.0 billion ahead of operating income growth due to higher income from associated companies (+173% cc), offset by higher financial expenses from the Alcon financing. Earnings per share (EPS) rose 16% (+17% cc) to USD 4.28 from USD 3.70 in the 2009 period. Core net income grew 17% (+18% cc) to USD 12.0 billion, while core EPS was up 14% (+15% cc) to USD 5.15 from USD 4.50 in the year-ago period.

The Board proposes a dividend payment of CHF 2.20 per share for 2010, up 5% from CHF 2.10 per share in 2009, representing the 14th consecutive dividend increase since the creation of Novartis in December 1996. Shareholders will vote on this and other proposals at the 2010 Annual General Meeting scheduled for February 22, 2011.

### Fourth quarter

Net sales rose 10% (+11% cc) to USD 14.2 billion. Alcon sales were USD 1.8 billion for the quarter. Unfavorable currency movements depressed the result by 1 percentage point (excluding Alcon). Recently launched products provided USD 2.5 billion of net sales in the 2010 period, which represent 20% of total sales (excluding Alcon).

Pharmaceuticals sales grew 3% (+4% cc) to USD 8.0 billion driven by 7 percentage points of volume expansion, offset by 3 percentage points of price erosion. Recently launched products contributed 23% of Pharmaceuticals sales, up from 18% in 2009. Sandoz maintained its strong growth (USD 2.4 billion, +10%, +14% cc) versus prior year, with 21 percentage points of volume expansion from new product launches, including gemcitabine (generic Gemzar®) and enoxaparin (generic Lovenox®). Vaccines and Diagnostics declined 74% (-73% cc) versus previous year to USD 361 million as a result of USD 1.0 billion of A(H1N1) pandemic flu vaccine sales in the fourth quarter of 2009 that were not repeated in the 2010 quarter and shipment delays resulting from production issues at one of our vaccines plants. Consumer Health growth (USD 1.6 billion, 0%, +1% cc) was suppressed by a high year-ago base due to the *Prevacid24HR* launch

and initial stocking in the OTC business unit. Excluding the launch impact of *Prevacid24HR* in 2009, Consumer Health growth in the fourth quarter of 2010 was 5% (+6% cc).

Operating income decreased 6% (-3% cc). Currency had a negative impact of 3 percentage points. Alcon contributed operating income of USD 222 million. One-off items in the quarter included charges totaling USD 789 million, partially offset by a gain of USD 392 million from the divestment of *Enablex*. These charges include Pharmaceuticals USD 253 million (mainly ASA404 impairment USD 120 million and US restructuring costs USD 85 million), Sandoz USD 49 million (German restructuring), Vaccines and Diagnostics USD 75 million (manufacturing restructuring USD 52 million and financial asset impairment USD 23 million), Alcon USD 383 million (fair value revaluation of inventory USD 372 million, costs resulting from the change in majority ownership USD 11 million) and Corporate charges of USD 24 million.

Excluding these one-time items and acquisition-related items, core operating income increased 2% in constant currencies to USD 3.2 billion. Core operating income margin decreased 2.5 percentage points to 22.3% of net sales. Included in the core operating margin decline of 2.5 percentage points was a benefit of 1.8 percentage points from Alcon while the absence of A(H1N1) pandemic flu vaccine sales in 2010 decreased the margin by 4.4 percentage points. Underlying margin excluding these two items was broadly flat.

Net income declined 2% to USD 2.3 billion. The decline was lower than operating income primarily as a result of a low tax charge stemming from the consolidation of Alcon and a true-up of the underlying Novartis tax rate to 16.3%, offset by higher Alcon-related financing costs and a decrease in income from associated companies (no Alcon equity accounting and inclusion of USD 89 million of Roche restructuring costs). Core net income was flat in constant currencies compared to 2009 at USD 2.8 billion.

Earnings per share (EPS) declined 6% (-2% cc) to USD 0.95 from USD 1.01 in the 2009 period, while core EPS was down 10% (-6% cc) in the fourth quarter to USD 1.14 from USD 1.26 in the year-ago period.

### Delivering innovation, growth and productivity

The long-term Novartis growth strategy is based on our focused, diversified portfolio. Following the expected completion of the merger with Alcon, the portfolio would be comprised of five divisions: Pharmaceuticals, Sandoz, Vaccines & Diagnostics, Consumer Health, and Alcon (eye care). The breadth of our portfolio focused on healthcare allows us to capture the most promising opportunities of the healthcare marketplace while at the same time mitigating the impact of challenges in particular sectors.

Our ability to execute this strategy delivering world-class healthcare solutions on a global scale, across all of our divisions comes from a commitment to three core priorities: (1) **extending our lead in innovation** through the research and development of new offerings and the expansion of applications for current offerings; (2) **accelerating growth across all divisions** with new launches and a greater presence in emerging markets; and (3) **enhancing productivity** through efficiency initiatives that free up resources for our R&D investment. By focusing on these priorities, we are able to sustain above-market growth, deliver value for investors, and improve healthcare outcomes for patients through new innovative solutions.

#### Extending our lead in innovation resulting in 13 approvals and 16 submissions in Pharmaceuticals

2010 was a landmark year for Novartis innovation, which resulted in 13 major approvals and 16 submissions in our Pharmaceuticals Division in the US, EU and Japan for the year, maintaining our productivity at the top end of the industry. Our pipeline remains strong: we currently have 147 projects in our Pharmaceuticals development pipeline; our early pipeline in Vaccines is progressing rapidly; and the Sandoz development organization is committed to investing in biosimilars and respiratory opportunities. Our unrivalled record in innovation allows us to maintain a high level of investment in R&D, enabling Novartis to make continuous progress in addressing areas of unmet patient need.

Novartis achieved important breakthroughs in 2010 in our continuing efforts to address unmet patient need. Among the most prominent of these accomplishments was the launch of *Gilenya* in the US, a first-line oral therapy for relapsing multiple sclerosis that has shown superior efficacy over standard of care, and *Menveo*, a new vaccine offering protection against four major serogroups of meningococcal disease, which infect more than a half million people each year. Sandoz demonstrated our ability to leverage innovation in order to create complex, cost-effective alternatives to branded drugs with the launch of enoxaparin and the significant progress in our biosimilar and respiratory portfolio.

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In the fourth quarter, several of our products were approved for critical new uses: *Afinitor* was approved in the US for patients with subependymal giant cell astrocytoma, a benign brain tumor associated with tuberous sclerosis; *Tasigna* gained approval in Europe, Japan and Switzerland as a first-line treatment for patients with newly diagnosed chronic myeloid leukemia (CML); and on January 6, 2011, *Lucentis* was approved in the EU for treatment of patients with diabetic macular edema, a major cause of blindness in the working-age population in most developed countries.

In the fourth quarter, a number of compounds in our pipeline took another step toward potential launch. Our 4CMenB vaccine candidate *Bexsero* was submitted for approval in the EU based on Phase III data from more than 7,500 subjects, which support the use of *Bexsero* in infants two months of age and older, as well as adolescents and adults. In Pharmaceuticals, the human monoclonal antibody ACZ885 was submitted in the EU for the treatment of gouty arthritis; *Lucentis* was submitted in the EU for the treatment of visual impairment due to retinal vein occlusion, in which the blood flow from the retina is interrupted; SOM230 was submitted in the EU for the treatment of Cushing s disease, a debilitating hormonal disorder for which there are currently no approved medicines; and *Afinitor* was submitted in the EU and the US for use in advanced neuroendocrine tumors, for which there are also currently no approved treatments.

Many of our medicines showed promise for expanded uses in addressing patient need. During the fourth quarter, a Phase II study of *Afinitor* suggested its application in the treatment of advanced breast cancer. An update of a longer-term Phase III study of *Tasigna* continued to show its superiority over *Gleevec/Glivec*, the long-time standard, in treating patients newly diagnosed with CML.

Phase III data of our oral Janus kinase (JAK) inhibitor INC424 showed significant clinical benefit in patients with myelofibrosis, an uncommon and debilitating blood cancer. Phase II data related to our oral investigational drug LBH589 suggested anticancer activity in some Hodgkin s lymphoma patients. Interim results of the AZURE trial for use of *Zomet*a in treating women with early breast cancer did not meet its primary endpoint, so we withdrew our applications.

A Phase III study of our influenza vaccine, *Fluad*, suggests efficacy in preventing influenza in young children. Based on successful clinical trial data supporting the immunogenicity and tolerability profile of *Menveo* in infants starting at two months of age, a supplemental Biologics License Application was submitted to the FDA for the use of *Menveo* in this age group.

#### Accelerating growth with recently launched products as key driver

Our strategy of rejuvenating our portfolio with new medicines continued to progress. Throughout 2010, recently launched products were a key driver of overall growth and an important factor in our ability to offset future patent expiries. In 2010, recently launched products accounted for USD 10.4 billion, or 21% of net sales; in the fourth quarter, they accounted for USD 2.5 billion, or 20% of net sales.

In 2010, Pharmaceuticals grew 7% (+6% cc) to USD 30.6 billion. Our strong momentum in innovation underpinned this growth with recently launched Pharmaceuticals products contributing USD 6.6 billion of net sales for the year, representing 21% of net sales compared to 16% in 2009. Europe, our largest region, had a strong year, growing 7% in constant currencies in spite of various government price cuts, harnessing recently launched products to drive 28% of net sales.

Sandoz delivered solid growth of 14% (+15% cc) in 2010, underpinned by strong results in US retail generics and biosimilars (+46% cc), which benefitted from the successful execution of first-to-market launches including enoxaparin, tacrolimus and losartan. Sandoz continues to lead in biosimilars with total 2010 sales of USD 185 million (+63% cc), based on key launches in the oncology indications of *Binocrit* (epoetin alfa) and *Zarzio* (filgrastim), as well as continued growth in *Omnitrope* (human growth hormone).

We were also successful in 2010 in the expansion of our presence in emerging markets. In 2010, sales (excluding Alcon) in our top six emerging markets, which include China, Russia, Brazil, India, South Korea and Turkey, were USD 4.6 billion growing 12% over the previous year. In the fourth quarter, sales were USD 1.2 billion, an increase of 1% over the year-ago period with A(H1N1) pandemic flu vaccine sales. We are committed to further expanding in these growing markets in order to meet patient and customer needs specific to these regions. In Russia, we demonstrated our commitment to becoming the government s leading healthcare partner, confirming our intent to build a new full-scale pharmaceutical manufacturing plant in St. Petersburg. This investment is part of an overall USD 500 million commitment in local infrastructure and collaborative healthcare initiatives planned over a five-year period.

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### Driving productivity with programs across all businesses

Productivity is an essential component of performance and remains a consistent focus. All parts of the business have extensive productivity programs to generate operating leverage. This provides the foundation for improved profitability while enabling investment for the future.

In the fourth quarter, we undertook a number of important measures to improve future productivity, incurring restructuring and impairment charges of USD 388 million. We realigned our US Pharmaceuticals field force, allowing us to become more adaptive to customer needs and focus on promising opportunities for growth in Specialty Care and other areas. We discontinued the ASA404 clinical trial program, allowing us to devote more resources to other cancer compounds in our pipeline, resulting in an impairment charge of USD 120 million. We also announced a restructuring of our Sandoz organization in Germany to adapt to the negative trend in the German generics market. Finally, in Vaccines and Diagnostics, we began implementation of a rationalization of our manufacturing facilities.

For the year 2010, core operating income margin increased 1.9 percentage points to 27.7%. The increase in sales of A(H1N1) pandemic flu vaccine over 2009 contributed 0.5 percentage points and Alcon 0.4 percentage points since it was consolidated from August 25, 2010. Of the balance of the margin increase of 1.0 percentage points, Marketing & Sales contributed 0.7 percentage points, R&D, General & Administration and Other Income and Expense a total of 0.7 percentage points, offset by a reduction in the gross margin of 0.4 percentage points. The underlying margin improvement was generated through continuing productivity initiatives that affect all four of the divisions in aggregate, productivity initiatives generated the equivalent of approximately 4 percentage points of margin improvement, enabling us to absorb most of the impact of price reductions on gross margin and to make investments to support recently launched products and future growth opportunities.

For the fourth quarter, core operating income margin decreased by 2.5 percentage points to 22.3%. Excluding the impact of Alcon (+1.8 percentage points) and sales of A(H1N1) pandemic flu vaccines in 2009 (-4.4 percentage points), core margin for the quarter increased by 0.1 percentage points. Gross productivity improvements in the quarter generated benefits equivalent to 4.4 percentage points of margin improvement. This benefit was absorbed by gross margin, mainly COGS (1.6 percentage points), with the balance reinvested in research and development and in support of the growth products.

#### <u>Alcon</u>

In the fourth quarter, the Novartis and Alcon Boards of Directors agreed on a merger, which we expect to be completed in the first half of 2011, which would raise our stake from 77% to 100%. Following the completion of the merger, Novartis will become the global leader in eye care, and add a fifth, high-growth division to its focused, diversified portfolio. The 100% ownership of Alcon would create new opportunities for immediate synergies between the two organizations, as Alcon would be able to benefit from the Novartis global scale while adding their eye care development and commercial expertise to the Group s capabilities.

Integration planning has started and the implementation steps necessary to create the new Alcon Division (which will include CIBA Vision and certain ophthalmic pharmaceutical products) and to realize the expected synergy benefits will commence after clearance of a registration statement by the US Securities and Exchange Commission, two-thirds approval by the shareholders of each of Novartis and Alcon voting at their respective meetings and other customary closing conditions.

### Cash flow and net indebtedness

The sustainability of our strategy lies with the generation of cash flow that provides the resources for reinvestment and creates shareholder return. Free cash flow before dividends generated USD 12.3 billion for the year 2010, rising 31% over the previous year, and in the fourth quarter totaled USD 4.2 billion, an increase of 25% over the previous period. The full year cash flow benefitted from A(H1N1) pandemic flu vaccine sales where cash was in excess of 2010 sales, while the fourth quarter cash generation included a number of one-off cash benefits.

Cash flow is driven by a continued focus on the cash conversion cycle and operational cash flow improvements. Cash flow from operating activities increased by USD 1.9 billion to USD 14.1 billion for 2010 (28% of net sales), and for the fourth quarter increased to USD 4.6 billion (32% of net sales).

Following the acquisition of a 77% majority stake in Alcon, the company moved from a net cash position to a net debt position. As of December 31, 2010, net debt stood at USD 14.9 billion, with USD 3.8 billion outstanding on the US commercial paper program, a reduction of USD 4.6 billion since the acquisition to date. The long-term credit rating for the company continues to be double-A (Moody s Aa2; Standard & Poor s AA-; Fitch AA).

#### 2011 Group outlook (Barring unforeseen events)

Group constant currency sales growth is expected to be around the double-digit mark.

Pharmaceuticals is expected to deliver sales growth in low- to mid-single-digits. Continued growth in recently launched products and emerging markets is expected to drive strong volume growth around the high-single-digit mark. Reported sales growth will be lower as a result of the combined effect of price reductions seen in 2010, the full impact of healthcare reform in the US and generic competition. *Femara* s patent will expire in the US in June 2011 and *Diovan* patents begin to expire in Europe in February 2011.

For Sandoz, sales growth of around mid-single-digits is expected. The aggressive launch program for new products and expansion in emerging markets is expected to continue. The exceptional sales growth experienced in 2010 in the US is unlikely to be maintained as exclusivity periods expire and if enoxaparin faces additional competitors. In addition, the healthcare cost-containment measures in Germany, experienced in the second half of 2010, are likely to be fully felt throughout 2011.

Alcon, Inc. has announced that it expects to increase sales at a high-single-digit rate in 2011.

With the continuing drive to generate productivity improvements across the Group, we aim to improve constant currency core operating income margin while absorbing price cuts, generic competition, the loss of sales from the A(H1N1) pandemic flu vaccine and investing for the future.

In 2011, we expect the full effect of Alcon acquisition accounting to result in amortization of intangible assets of approximately USD 2.0 billion.

From January 1, 2011, research costs of USD 195 million, currently included in Corporate expenses, will be recorded in Pharmaceuticals.

#### **Annual General Meeting**

### **Election of Members to the Novartis Board of Directors**

At the Annual General Meeting scheduled for February 22, 2011, the Novartis Board of Directors proposes the re-election of Mr. Pierre Landolt, Dr. Ulrich Lehner and Mrs. Ann Fudge, each for a three-year term. In addition, Alexandre Jetzer-Chung and Hans-Joerg Rudloff will retire from the Board as they have reached the statutory age limit. The Board and management team of Novartis thank Mr. Jetzer-Chung and Mr. Rudloff for their many years of distinguished services on the Novartis Board of Directors.

The Board further recommends the election of Dr. Enrico Vanni to the Novartis Board of Directors for a three year term. Dr. Vanni, a Swiss citizen, has more than 30 years of healthcare management experience. He is a chemical engineer and graduated from the Federal Polytechnic School of Lausanne, Switzerland and holds a PhD (Doctorate in Science) from the University of Lausanne. His background also includes an MBA from INSEAD in Fontainebleau, France. Dr. Vanni managed the Geneva Office of McKinsey&Company from 1988 to 2004. His consulting activities mostly covered companies in the pharmaceutical, consumer and finance sectors. He was head of the European pharmaceutical practice for McKinsey&Company and served as member of the Partner review committee of the firm. Since 2008, he is an independent consultant and member of several company boards of directors, including Alcon.

### Consultative Vote on the Novartis Compensation System

At last year s Annual General Meeting, Novartis shareholders approved the proposal by the Board of Directors to introduce a consultative vote on the compensation system in the Articles of incorporation (a so called say on pay - vote). The upcoming Annual General Meeting, to be held on February 22, 2011, will provide shareholders an opportunity to express their views on the compensation system of Novartis through a consultative vote. Subsequently, non-binding votes will be held before every significant change in the compensation system, but at a minimum at every third Annual General Meeting.

### HEALTHCARE BUSINESS REVIEW

### **Pharmaceuticals**

	Q4 2010	Q4 2009	% change		FY 2010	FY 2009	% char	ıge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	8 032	7 773	3	4	30 558	28 538	7	6
Operating income	2 290	1 906	20	25	8 798	8 392	5	6
As % of net sales	28.5	24.5			28.8	29.4		
Core operating income	2 274	2 215	3	7	9 909	9 068	9	10
As % of net sales	28.3	28.5			32.4	31.8		

### <u>Full year</u>

#### Net sales

Net sales expanded 7% (+6% cc) to USD 30.6 billion driven by 8 percentage points of volume expansion, partly offset by a negative pricing impact of 2 percentage points. Recently launched products provided USD 6.6 billion of net sales in the 2010 period, representing 21% of net sales compared to 16% in the 2009 period.

Europe remained the largest region (USD 10.9 billion, +7% cc) particularly benefiting from recently launched products generating 28% of its net sales. The US (USD 10.0 billion, +5% cc), as well as Latin America and Canada (USD 2.9 billion, +14% cc), maintained solid growth rates. Japan s performance (USD 3.3 billion, 0% cc) was flat versus prior year due to the bi-annual price cuts and ARB market slowdown. The top six emerging markets (USD 2.9 billion, +9% cc) were led by double-digit growth from India, Russia, South Korea and China, partly offset by the impact of cost-containment measures in Turkey.

#### **Operating income**

Operating income grew 5% (+6% cc) to USD 8.8 billion. The operating income margin of 28.8% of net sales was mainly impacted by R&D impairments of USD 896 million, litigation charges of USD 181 million and restructuring expenses of USD 111 million, partly offset by divestment income of USD 425 million and the *Famvir* settlement with Teva.

Core operating income grew 9% (+10% cc) ahead of sales to USD 9.9 billion. The core operating income margin of 32.4% of net sales improved 0.6 percentage points. Cost of Goods Sold remained broadly stable, while total functional costs improved 0.8 percentage points due to continuing productivity improvements. Other Income and Expense increased 0.2 percentage points mainly due to higher pre-launch inventory provisions.

### Fourth quarter

### Net sales

Net sales grew 3% (+4% cc) to USD 8.0 billion, driven by 7 percentage points volume growth, partly offset by a negative pricing impact of 3 percentage points (mainly due to European government cost-containment measures and the bi-annual price cut in Japan). Products launched since 2007 generated USD 1.8 billion of net sales, growing 34% cc over the same period last year. These recently launched products which include *Lucentis, Exforge, Exelon* Patch, *Exjade, Reclast/Aclasta, Tekturna/Rasilez, Tasigna, Afinitor, Onbrez Breezhaler, Ilaris, Fanapt* and *Gilenya* now comprise 23% of division sales compared to 18% in the 2009 quarter.

Recently launched products benefited all regions, particularly Europe (USD 2.9 billion, +5% cc), which generated 30% of its net sales from these products. Volume growth in Europe was 12 percentage points with a negative price effect of 7 percentage points due to recent government cost-containment measures. The US (USD 2.5 billion, +2% cc) showed modest growth, while Latin America and Canada (USD 0.8 billion, +13% cc) maintained solid growth rates. Japan s sales (USD 1.0 billion, -1% cc) declined slightly versus the same period last year due to the bi-annual price cuts and the angiotensin II receptor blocker (ARB) market slowdown. The top six emerging markets (USD 769 million, +6% cc) were led by particularly strong growth in India, Russia and South Korea, more than compensating for slower growth in Turkey and China due to cost-containment measures and stock-in-trade effects, respectively.

All strategic franchises contributed to the business expansion. Oncology (USD 2.7 billion, +10% cc), the largest franchise, was led by the sustained growth of *Gleevec/Glivec* (USD 1.1 billion, +6% cc), *Sandostatin* (USD 351 million, +12% cc) and *Femara* (USD 351 million, +5% cc). Recently launched Oncology products

made important contributions: *Tasigna* (USD 126 million, +89% cc), *Afinitor* (USD 80 million, +164% cc) and *Exjade* (USD 209 million, +14% cc). The Cardiovascular and Metabolism franchise (USD 2.1 billion, +5% cc) maintained solid momentum supported by hypertension medicines (USD 2.0 billion, +4% cc) and the continued strong uptake of *Galvus* (USD 124 million, +96% cc). The Neuroscience and Ophthalmics franchise (USD 1.0 billion, +5% cc) saw solid growth from *Lucentis* (USD 394 million, +8% cc), *Extavia* (USD 40 million, +83% cc), and the recently launched *Gilenya*, which is off to a good start in the US.

#### **Operating income**

Operating income increased 20% (+25% cc) to USD 2.3 billion, primarily due to the US legal provision for *Trileptal* in the same period last year and the *Enablex* divestment income of USD 392 million in 2010, partly offset by the ASA404 impairment charges of USD 120 million and restructuring charges of USD 85 million.

Core operating income grew 3% (+7% cc) ahead of sales to USD 2.3 billion. The core operating income margin of 28.3% of net sales decreased slightly by 0.2 percentage points compared to the same period last year as currency fluctuations negatively impacted the operating income margin by 1.0 percentage points. Gross margin improved by 1.6 percentage points due to production productivity improvements. R&D increased 1.3 percentage points of net sales mainly driven by the phasing of clinical trial activities, while Marketing & Sales and General & Administration expenses improved 0.3 percentage points, benefiting from continued productivity efforts and despite increased investments in new launches. Other Income and Expense increased 0.7 percentage points mainly due to the phasing of one-time items and higher pre-launch inventory provisions.

### **Pharmaceuticals product review**

### **Cardiovascular and Metabolism**

	Q4 2010 USD m	Q4 2009 USD m	% chai USD	nge cc	FY 2010 USD m	FY 2009 USD m	% cha USD	nge cc
Hypertension medicines	000 111	000 m	0.52	u	000 11	000 m	000	
Diovan	1 576	1 614	-2	-3	6 053	6 013	1	0
Exforge	251	196	28	31	904	671	35	35
Tekturna/Rasilez	133	88	51	54	438	290	51	53
Subtotal	1 960	1 898	3	4	7 395	6 974	6	5
Galvus	124	66	88	96	391	181	116	122
Lotrel	42	78	-46	-45	266	322	-17	-18
Total strategic								
products	2 126	2 042	4	5	8 052	7 477	8	7
Established medicines								
(Lescol included)	267	322	-17	-17	1 103	1 319	-16	-17
Total	2 393	2 364	1	0	9 155	8 796	4	4

All comments below focus on fourth quarter movements.

Our broad cardiovascular and metabolic portfolio continued to grow with larger contributions from *Tekturna* and *Galvus/Eucreas* offsetting slightly declining *Diovan* sales in the fourth quarter of 2010. Overall, the franchise recorded sales growth of 4% cc versus previous year.

*Diovan* Group (USD 1.6 billion, -3% cc; FY 2010 USD 6.1 billion, 0% cc) worldwide sales declined 3% in constant currencies in the fourth quarter versus 2009, but maintained its sales performance for the full year 2010 despite the introduction of generic losartan. In the US, the *Diovan* Group achieved sales of USD 648 million (0% cc) in the quarter, maintaining its leadership in the ARB segment with a 41.5% share in November year-to-date 2010 (+2.1 percentage points compared to November year-to-date 2009; source: IMS Health). We anticipate increased generic competition as the patent on valsartan, the active ingredient in *Diovan* Group products, expires in the major countries of the EU during 2011.

*Exforge* Group (USD 251 million, +31% cc; FY 2010 USD 904 million, +35% cc) showed strong worldwide growth fueled by continued prescription demand in the EU, US and other key regions, as well as ongoing *Exforge HCT* launches in European and Latin American markets. *Exforge*, a single-pill combination of *Diovan* (valsartan) and the calcium channel blocker amlodipine, has delivered sustained growth across world markets since its launch in 2007. *Exforge HCT*, the first modern triple hypertension medication that adds a diuretic in a single pill, was introduced in the US in 2009 and has gained approvals in over 20 countries worldwide.

*Tekturna/Rasilez* (USD 133 million, +54% cc; FY 2010 USD 438 million, +53% cc) maintained its strong growth driven by excellent performance in the EU, especially in France and Germany. In December, the FDA approved *Amturnide*, a single-pill combination of aliskiren, amlodipine and hydrochlorothiazide, with EU review of this treatment ongoing. *Amturnide* will be launched in the US in January 2011.

*Galvus* Group (USD 124 million, +96% cc; FY 2010 USD 391 million, +122% cc), oral treatments for type 2 diabetes, continued to deliver strong growth. This was driven mainly by combination treatment *Eucreas/Galvusmet*, which contributed 71% of total sales and grew at 95% in constant currencies during the fourth quarter versus the prior year. Growth across the *Galvus* group of products was driven by France, Germany, Portugal and Spain. Further growth is expected in Japan following an agreement with Sanofi-Aventis K.K. in November to co-promote *Galvus*, known as *Equa* in Japan.

### Oncology

	Q4 2010	Q4 2009	% change	<u>!</u>	FY 2010	FY 2009	% chan	ige
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Bcr-Abl Franchise								
Gleevec/Glivec	1 143	1 086	5	6	4 265	3 944	8	7
Tasigna	126	68	85	89	399	212	88	89
Subtotal	1 269	1 154	10	11	4 664	4 156	12	11
Zometa	395	392	1	1	1 511	1 469	3	2
Femara	351	341	3	5	1 376	1 266	9	9
Sandostatin	351	316	11	12	1 291	1 155	12	11
Exjade	209	183	14	14	762	652	17	16
Afinitor	80	32	nm	nm	243	70	nm	nm
Other	37	51	-27	-28	181	231	-22	-23
Total	2 692	2 469	9	10	10 028	8 999	11	11

nm not meaningful

Our Bcr-Abl franchise, consisting of *Gleevec/Glivec* and *Tasigna*, continued to grow strongly, reaching USD 1.3 billion (+11% cc) in the fourth quarter (FY 2010 USD 4.7 billion, 11% cc).

*Gleevec/Glivec* (USD 1.1 billion, +6% cc; FY 2010 USD 4.3 billion, +7% cc), a targeted therapy, has sustained growth through continued expansion in Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) as well as adjuvant (post-surgery) treatment of gastrointestinal stromal tumors (GIST). *Gleevec/Glivec* was approved in 2009 for use in adjuvant treatment of patients following complete gross resection of GIST and has since received approvals for this indication in 57 countries.

*Tasigna* (USD 126 million, +89% cc; FY 2010 USD 399 million, +89% cc) has been growing rapidly as a next generation targeted therapy for newly diagnosed CML patients supported by approvals in several key markets, increased share in the imatinib resistant/intolerant CML market, as well as geographic and market expansion. *Tasigna* is now approved in the US, EU, Japan, Switzerland and other countries for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. Regulatory submissions in the first-line indication have also been submitted to other countries around the world.

*Zometa* (USD 395 million, +1% cc; FY 2010 USD 1.5 billion, +2% cc) is a leading treatment to reduce or delay skeletal-related events in patients with bone metastases (cancer that has spread to the bones) from solid tumors and multiple myeloma. The AZURE trial, to investigate the potential use of *Zometa* as adjuvant therapy in premenopausal and postmenopausal women with early breast cancer, did not meet its primary endpoint in the overall patient population. However, in a predefined subgroup of women with well-established menopause, an improvement in disease-free survival and overall survival was shown in the *Zometa* arm. Regulatory filings in the US and EU for the potential use of *Zometa* for adjuvant breast cancer treatment have been withdrawn, and Novartis will discuss future regulatory plans with health authorities worldwide based on these data. Zoledronic acid, the active ingredient in *Zometa* (4 mg), is also available under the trade names *Reclast/Aclasta* (5 mg) for use in non-oncology indications with different dosing. *Zometa* is facing new competition from denosumab, a product of Amgen.

*Femara* (USD 351 million, +5% cc; FY 2010 USD 1.4 billion, +9% cc), a treatment for early stage or advanced breast cancer in postmenopausal women, achieved strong sustained growth in key markets. We anticipate new generic competition in the US in the first half of 2011 and later in the year in Europe s major markets.

*Sandostatin* (USD 351 million, +12% cc; FY 2010 USD 1.3 billion, +11% cc) benefited from the increasing use of *Sandostatin LAR* in treating symptoms of patients with neuroendocrine tumors.

*Exjade* (USD 209 million, +14% cc; FY 2010 USD 762 million, +16% cc) continued to expand with strong growth based on new patients, expanded access and increased dosing in the US and key markets around the world. *Exjade* is currently approved in more than 100 countries as the only once-daily oral therapy for transfusional iron overload.

*Afinitor* (USD 80 million; FY 2010 USD 243 million), an oral inhibitor of the mTOR pathway used across multiple diseases, expanded its indications in the US with an accelerated FDA approval for the treatment of patients with subependymal giant cell astrocytoma (SEGA), a benign brain tumor associated with tuberous sclerosis, who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of *Afinitor* is based on a 28-patient Phase II study. A Phase III study to further explore the clinical benefits of *Afinitor* for patients with SEGA associated with tuberous sclerosis has completed enrollment. We have also filed regulatory submissions in the EU for this indication under the trade name *Votubia. Afinitor* is also an approved treatment for advanced renal cell carcinoma (kidney cancer) following VEGF-targeted therapy. We have filed *Afinitor* for the treatment of advanced neuroendocrine tumors (NET) in the US and EU. Submissions for the treatment of patients with advanced NET are also underway in other countries. Everolimus, the active ingredient in *Afinitor*, is also available under the trade names *Zortress/Certican* for use in non-oncology indications. Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

#### **Neuroscience and Ophthalmics**

	Q4 2010	Q4 2009	% change	e	FY 2010	FY 2009	% cha	ıge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Lucentis	394	374	5	8	1 533	1 232	24	24
Exelon/Exelon Patch	256	267	-4	-1	1 003	954	5	6
Comtan/Stalevo	157	152	3	4	600	554	8	8
Extavia	40	23	74	83	124	49	nm	nm
Other	114	116	-2	0	457	459	0	-1
Total strategic products	961	932	3	5	3 717	3 248	14	14
Established medicines	148	149	-1	-4	567	575	-1	-4
Total	1 109	1 081	3	3	4 284	3 823	12	11

nm not meaningful

*Lucentis* (USD 394 million, +8% cc; FY 2010 USD 1.5 billion, +24% cc) maintained its strong growth this year as the only approved medicine to significantly improve vision in patients with wet age-related macular degeneration (AMD). Growth in the fourth quarter was negatively impacted by a one-time provision. *Lucentis* is approved in more than 85 countries for the treatment of wet AMD. The European Commission granted Novartis a new indication for *Lucentis* for the treatment of visual impairment due to diabetic macular edema. Novartis also filed an application in the EU in the fourth quarter of 2010 for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion. Genentech holds the rights for *Lucentis* in the US.

*Exelon/Exelon* Patch (USD 256 million, -1% cc; FY 2010 USD 1 billion, +6% cc) sales growth declined versus the previous year as a consequence of healthcare cost-containment measures in various markets, but achieved 2,% volume growth in the quarter and 7% volume growth for the full year. Due to increasing demand, *Exelon* Patch, the transdermal form of the medicine, generated more than 74% of total *Exelon* sales in the fourth quarter compared to 58% in the same period in 2009. *Exelon* Patch is approved for the treatment of mild-to-moderate Alzheimer s disease dementia in more than 75 countries, including more than 20 countries where it is also approved for dementia associated with Parkinson s disease.

*Extavia* (USD 40 million, +83% cc; FY 2010 USD 124 million) continued to grow within key markets, notably Germany, Russia, Italy and Spain. *Extavia*, the Novartis-branded version of Betaferon®/Betaseron® for relapsing forms of multiple sclerosis, was launched in the EU and US in 2009, and has been approved in over 30 countries.

*Gilenya* (USD 11 million; FY 2010 USD 15 million) has been launched as a first-line treatment for relapsing forms of multiple sclerosis in the US and for relapsing-remitting multiple sclerosis in Russia. It was also approved as a first-line treatment for relapsing forms of multiple sclerosis in Australia, Switzerland and the United Arab Emirates. In January 2011, *Gilenya* received a positive opinion from Europe s Committee for Medicinal Products for Human Use (CHMP) as a disease modifying therapy in patients with highly active relapsing-remitting multiple sclerosis (RRMS) despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS. *Gilenya* is currently under regulatory review in other countries around the

world, including Canada, Turkey and Brazil. Initial sales uptake in the US has been in line with expectations, with sales of USD 13 million since its launch in October 2010.

### Respiratory

	Q4 2010	Q4 2009	% cha	ange	FY 2010	FY 2009	% cha	ange
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Xolair	102	120	-15	-11	369	338	9	12
TOBI	72	81	-11	-11	279	300	-7	-7
Onbrez Breezhaler	17	1	nm	nm	33	1	nm	nm
Total strategic								
products	191	202	-5	-3	681	639	7	9
Established medicines	48	55	-13	-9	174	190	-8	-10
Total	239	257	-7	-5	855	829	3	4

nm not meaningful

*Xolair* (USD 102 million, -11% cc; FY 2010 USD 369 million, +12% cc), a biotechnology drug for severe persistent allergic asthma in Europe and for moderate-to-severe persistent allergic asthma in the US, continued to show strong growth in major European and Latin American markets. Fourth quarter growth was impacted by Genentech s order patterns. *Xolair* is approved in more than 85 countries, and a Phase III trial is progressing to support registration in China. *Xolair* Liquid, a new formulation in pre-filled syringes to enable easier administration than with the conventional lyophilized formulation, is expected to launch in Europe in 2011.

*Onbrez Breezhaler* (USD 17 million; FY 2010 USD 33 million) has demonstrated strong sales growth since its approval in the EU in November 2009 as a once-daily long-acting beta-2 agonist for adults with chronic obstructive pulmonary disease. *Onbrez Breezhaler* is now approved in more than 40 countries and is available in 13 European markets, with additional launches planned in 2011. The application for US approval (under the trade name *Arcapta Neohaler*) is expected to be reviewed by an FDA Advisory Committee in March 2011.

#### **Integrated Hospital Care**

	Q4 2010	Q4 2009	% cha	% change		FY 2009	% change	
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Neoral/Sandimmun	235	244	-4	-4	871	919	-5	-7
Reclast/Aclasta	171	147	16	18	579	472	23	23
Myfortic	114	97	18	19	444	353	26	23
Zortress/Certican	39	36	8	13	144	118	22	25
Ilaris	10	2	nm	nm	26	3	nm	nm
Other	79	70	13	15	293	235	25	24
Total strategic products	648	596	9	10	2 357	2 100	12	11
Established medicines	229	235	-3	-5	890	941	-5	-7
Total	877	831	6	3	3 247	3 041	7	5

nm not meaningful

**Reclast/Aclasta** (USD 171 million, +18% cc; FY 2010 USD 579 million, +23% cc), the once-yearly osteoporosis therapy, continued to show sustained growth in the fourth quarter and throughout the year driven by key countries including the US, France and Australia and by recent launches such as Turkey. *Aclasta* is approved in over 90 countries for up to six indications across a broad spectrum of patients, including those with early bone loss to patients with more severe forms of this metabolic bone disease. Six-year data from a pivotal fracture trial reinforced the long-term efficacy and safety profile of *Aclasta*. Zoledronic acid, the active ingredient in *Reclast/Aclasta*, is also available in a number of countries in a different dosage for use in oncology indications under the trade name *Zometa*.

**Zortress/Certican** (USD 39 million, +13% cc; FY 2010 USD 144 million, +25% cc), available in more than 80 countries to prevent organ rejection in adult kidney and heart transplantation, continues to generate solid growth, including the US launch in April 2010 for adult kidney transplantation under the trade name *Zortress*. Recent two-year data from a large Phase III registration study showed that everolimus, the active ingredient in *Zotress/Certican*, maintained efficacy and renal function with a mean dose of cyclosporine reduced by 60% versus the standard of care in kidney transplant recipients. Phase III development of everolimus for liver transplantation is ongoing. Everolimus is also available under the trade name *Afinitor* for use in certain oncology indications, and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

*Ilaris* (USD 10 million; FY 2010 USD 26 million) is a fully human monoclonal antibody that selectively binds and neutralizes IL-1 $\beta$ , a pro-inflammatory cytokine. Since 2009, *Ilaris* has been approved in over 40 countries for the treatment of adults and children aged four years and older suffering from cryopyrin-associated periodic syndrome, a group of rare auto-inflammatory disorders that affect approximately one out of one million people. ACZ885 (*Ilaris*, canakinumab) has been filed in Europe for the treatment of gouty arthritis attacks based on data from two Phase III registration studies that met their primary endpoints.

### Vaccines & Diagnostics

	Q4 2010	Q4 2009	% cha	inge	FY 2010	FY 2009	% cha	nge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	361	1 387	-74	-73	2 918	2 424	20	25
Operating income	-253	583	nm	nm	612	372	65	87
As % of net sales	-70.1	42.0			21.0	15.3		
Core operating income	-121	653	nm	nm	1 066	719	48	58
As % of net sales	-33.5	47.1			36.5	29.7		

nm Not meaningful

### Full year

#### Net sales

Net sales were USD 2.9 billion for the full year 2010 ( $\pm 25\%$  cc) compared to USD 2.4 billion for the year-ago period. Deliveries for supply contracts with governments around the world for A(H1N1) pandemic flu vaccines and adjuvants generated net sales of USD 1.3 billion, significantly driving the increase over the year-ago period. Excluding the A(H1N1) pandemic flu, the business experienced strong growth ( $\pm 16\%$  cc) driven by the strong seasonal flu season, the expansion of the vaccines business in emerging markets and the launch of *Menveo*.

#### **Operating income**

Operating income in the period was USD 612 million compared to USD 372 million in the year-ago period, driven substantially by the increased contribution of A(H1N1) pandemic flu vaccines.

We continued to invest heavily in the development of our late stage pipeline and increased marketing resources to successfully launch *Menveo* globally. Full year operating income was additionally impacted by a USD 98 million impairment charge related to a financial asset, USD 52 million in restructuring charges related to the consolidation of our manufacturing facilities, and a USD 45 million legal settlement expense.

Despite heavy investment in R&D and Marketing & Sales, core operating income increased by 48% (+58% cc) to USD 1.1 billion, after adjusting for the impairment charges, restructuring charges and legal settlement noted above, as well as the amortization of intangible assets.

### Fourth quarter

#### Net sales

Net sales were USD 361 million for the fourth quarter of 2010 (-73% cc) compared to USD 1.4 billion in the prior period. The primary driver of net sales variance against the prior year period was USD 1.0 billion of A(H1N1) pandemic flu vaccine sales in the fourth quarter of 2009 that were not repeated in the same period in 2010.

Excluding the impact of the A(H1N1) pandemic flu in both years, there was strong growth in the quarter in our meningococcal disease franchise offset by shipment delays resulting from production issues at one of our vaccines plants.

#### **Operating income**

Operating loss was USD 253 million for the quarter compared to an operating income of USD 583 million for the same period in 2009. In addition to the amortization of intangible assets, operating income included restructuring efforts to better align our manufacturing facilities worldwide, which resulted in a USD 52 million charge in the fourth quarter of 2010. In addition, the quarter included an impairment charge of USD 23 million related to a financial asset.

Core operating loss for the period was USD 121 million compared to an operating income of USD 653 million for the year-ago period. This was largely due to the operating income associated with the A(H1N1) pandemic flu vaccine sales from the prior year quarter not being repeated in the fourth quarter of 2010 and the impact of the shipment delays noted above.

In the quarter, our 4CMenB vaccine candidate *Bexsero* was submitted for approval in the EU. *Menveo*, our breakthrough vaccine for meningococcal disease, was submitted to the FDA for use in infants two months of ge and older. In addition, our adjuvanted seasonal influenza vaccine *Fluad* was submitted for approval in the EU for use in young children.

### Sandoz

	Q4 2010	Q4 2009	% cha	nge	FY 2010	FY 2009	% cha	nge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	2 367	2 143	10	14	8 518	7 493	14	15
Operating income	258	221	17	14	1 272	1 071	19	18
As % of net sales	10.9	10.3			14.9	14.3		
Core operating income	379	356	6	6	1 685	1 395	21	21
As % of net sales	16.0	16.6			19.8	18.6		

### <u>Full year</u>

#### Net sales

Sandoz achieved double-digit sales growth in 2010 (USD 8.5 billion, +14%, +15% cc) versus prior year driven by strong growth in US retail generics and biosimilars (+46% cc) and emerging markets. Volume expanded 22 percentage points due to new product launches, the inclusion of EBEWE Pharma s specialty generics business (contributing 4 percentage points) and continued strong results from biosimilars which together more than compensated for price erosion of 7 percentage points. German retail generics and biosimilars declined by USD 100 million (-6% cc) as the market was impacted by numerous healthcare reforms.

US sales growth in 2010 was driven by successful execution of new product launches including enoxaparin (USD 462 million), tacrolimus (USD 184 million), losartan (USD 145 million), lansoprazole (USD 123 million) and gemcitabine (USD 58 million). Sandoz s enoxaparin exclusivity in the US could change at any time, whereas lansoprazole ODT and gemcitabine will face increased competition in the US in April and May 2011, respectively.

Biosimilar sales expanded rapidly (+63% cc) to USD 185 million.

#### **Operating income**

Operating income grew 19% (+18% cc) versus prior year to USD 1.3 billion. The operating income margin increased 0.6 percentage points to 14.9% of net sales, an all-time high for Sandoz. The operating income margin increase of 0.6 percentage points includes acquisition-related charges for the integration of EBEWE Pharma, one-time charges for the termination of a co-development agreement, provisions for legal settlements and higher levels of restructuring charges than in the prior year, totalling -0.6 percentage points.

Core operating income rose 21% (+21% cc) to USD 1.7 billion, as the core operating income margin improved by 1.2 percentage points to 19.8% of net sales. There were lower sales to other divisions and other revenues (-0.4 percentage points) and higher Cost of Goods Sold (-1.2 percentage points). These impacts were more than offset by a number of positive factors, including: Marketing & Sales costs, which were lower by 0.7 percentage points due to productivity improvements partly offset by investments in growth areas; R&D costs, which decreased (+0.7 percentage points) as reduced investments in standard generics and productivity savings (+1.4 percentage points) funded increasing investment in the development of differentiated generics (-0.6 percentage points); General & Administration costs, which decreased (+1.0 percentage points) due to ongoing cost reduction measures; and Other Income and Expense, which were positive at 0.2 percentage points due to lower legal fees.

### Fourth quarter

Net sales

Sandoz grew strongly (USD 2.4 billion, +10%, +14% cc) versus prior year with 21 percentage points of volume expansion from new product launches, including a successful gemcitabine launch (generic

Gemzar®); continued enoxaparin exclusivity (generic Lovenox®); strong performance in the US, Russia, UK, Turkey and Japan; and accelerating biosimilars growth, which more than offset the price erosion of 7 percentage points.

US retail generics and biosimilars (+44% cc) continued to deliver excellent growth due to the successful execution of first-to-market launches including enoxaparin (USD 170 million), gemcitabine, tacrolimus and lansoprazole oral dispersible tablets (ODT). Sandoz s enoxaparin exclusivity in the US could change at any time, whereas lansoprazole ODT and gemcitabine will face increased competition in the US in April and May 2011, respectively.

German retail generics and biosimilars declined by USD 38 million (-9% cc) compared to the prior year, though by less than the estimated negative net market decline of 22% in the quarter driven by the impact of statutory health insurance tenders and new lower reference prices. Western Europe retail generics and biosimilars (+8% cc) grew positively despite various government price cuts. Emerging markets growth was strong in the Middle East, Turkey and Africa (+30% cc), Asia-Pacific (+13% cc), and Central and Eastern Europe (+13% cc). Sandoz sustained its leading global position in biosimilars (+72% cc) with good momentum based on key launches in the oncology indications of *Binocrit* (epoetin alfa) and *Zarzio* (filgrastim), as well as continued growth in *Omnitrope* (human growth hormone).

### **Operating income**

Operating income grew 17% (+14 cc) to USD 258 million, as the operating income margin improved 0.6 percentage points to 10.9% of net sales. This increase includes 1.1 percentage points of benefits from the impact of EBEWE Pharma acquisition-related charges in 2009 partly offset by higher charges for the restructuring in Germany in 2010 (USD 49 million).

Core operating income rose 6% (+6% cc) to USD 379 million, with a decline in core operating income margin by 0.6 percentage points to 16.0% of net sales. Gross profit margin decreased 2.1 percentage points mainly due to a significantly different sales mix than in the prior year quarter, which particularly reflects higher low-margin sales in the US and lower high-margin sales in Germany. Marketing & Sales (16.9% of net sales, +1.6 percentage points) improved core operating income margin due to higher productivity, while fully funding investments in growing businesses. R&D costs increased (8.4% of net sales, -0.3 percentage points) due to continued investment in the development of differentiated generics (-1.1 percentage points) such as biosimilars and respiratory products partly offset by reduced investment and productivity savings elsewhere (+0.8 percentage points). General & Administration costs (4.0% of net sales, +1.1 percentage points) due to ongoing cost-containment measures. Other Income and Expense increased (2.1% of net sales, -0.9 percentage points) mainly due to the cost of litigation and legal settlements.

### **Consumer Health**

	Q4 2010	Q4 2009	% chan	ıge	FY 2010	FY 2009	% cha	nge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	1 630	1 623	0	1	6 204	5 812	7	6
Operating income	209	207	1	10	1 153	1 016	13	17
As % of net sales	12.8	12.8			18.6	17.5		
Core operating income	237	248	-4	3	1 253	1 118	12	15
As % of net sales	14.5	15.3			20.2	19.2		

### <u>Full year</u>

### Net sales

Sales grew 7% (+6% cc) to USD 6.2 billion and all Consumer Health businesses delivered growth ahead of their respective markets for the full year.

All regions contributed to sales growth in OTC (+5% cc), supported by double-digit growth of the key brands *Voltaren, Nicotinell* and *Excedrin. Pantoloc Control* was successfully launched in 14 European markets in 2010 and is expected to continue to support growth in the gastrointestinal franchise. Retail sales of *Prevacid24HR* have driven the Novartis OTC business in the US to be the fastest growing in its peer group, while *Excedrin* established itself as a top four brand in its category and as the second fastest growing brand among its competitors.

CIBA Vision (+6% cc) continues to show robust growth in the growing contact lens and lens care markets on the strength of *AirOptix* across all regions. *AirOptix Aqua Multifocal* lens continues to grow after becoming the number one lens for presbyopic users in April 2010, less than 12 months after its launch. Launches of *FreshLook Illuminate* in Asia and Japan contributed to 2010 growth, and *ClearCare*, CIBA Vision s leading peroxide-based lens disinfectant solution, experienced its third year of double-digit growth as users continue to migrate to its clinically proven one-bottle regimen.

Animal Health growth (+7% cc) was led mainly by the strong performance of *Interceptor* and *Sentinel* in the US and *Milbemax* in Europe, as well as by the robust growth of cattle vaccines in the US livestock market. Overall, the cattle and sheep brands in key markets, including the US and Australia, and the companion animal parasiticides fueled the high-single-digit business growth in 2010.

The US business grew 6%, supported by a double-digit growth rate in CIBA Vision and a high-single digit growth rate in Animal Health. Net sales in the top six emerging markets experienced solid growth (USD 0.5 billion, +10% cc), with Russia, Turkey, India and South Korea standing out with double-digit growth rates.

#### **Operating income**

Operating income rose 13% (+17% cc) to USD 1.2 billion, with the operating income margin improving over full year 2009 by 1.1 percentage points, to 18.6% of net sales for 2010.

Excluding the impact of currency movements, the division showed a strong operating leverage by growing operating income 17% in constant currencies, at nearly three times the rate of sales growth.

Core operating income rose 12% (+15% cc) to USD 1.3 billion, with strong operating leverage driving the core operating income margin up 1.0 percentage points to 20.2% of net sales versus 2009. Gross margin improvements (+1.3 percentage points), productivity gains, and income from an OTC US non-core brand divestment (Other Income and Expense +0.2 percentage points) have been the key growth drivers, partially offsetting higher investments in Marketing & Sales (-0.8 percentage points) to support new product launches and geographic expansion.

### Fourth quarter

#### Net sales

The three Consumer Health businesses OTC, Animal Health and CIBA Vision together delivered flat net sales in the fourth quarter of 2010 (USD 1.6 billion, 0%, +1% cc). Comparative performance in the quarter was affected by the *Prevacid24HR* launch in the OTC business unit in November 2009.

Excluding the launch impact of *Prevacid24HR in the prior year*, Novartis Consumer Health fourth quarter sales reflected continued growth in line with prior quarters (+5%, +6% cc). Key brands in all three businesses continued to make market share gains in the quarter.

Pain medicines were key contributors in OTC, again led by *Voltaren*, which has been a key business driver, and *Excedrin*, which gained significant share in the market segment in the quarter. *Voltaren* delivered 16% growth in the quarter and maintained its position in Germany as the country s largest self-medication brand. *Prevacid24HR* maintained a 20% market share in the large and growing US proton pump inhibitor heartburn market. In the fourth quarter, *Prevacid24HR* became the number two Novartis OTC brand in the US for the year, behind *Excedrin*, and established itself as one of the top twenty OTC brands.

CIBA Vision experienced continued robust growth from its key brand *AirOptix*, which grew rapidly in the period in all regions. US, Latin America, Russia and Turkey, with double-digit sales growth in the period, were key contributors for the business.

Several Animal Health markets, particularly in Asia-Pacific, Latin America, and Eastern and Northern Europe, delivered strong growth. The US continued to gain market share with key contributions from *Interceptor* and *Sentinel*. *Milbemax* grew rapidly in Europe, and a strong and early endo- and ecto-parasite season in Australia drove performance of Zolvix, Vetrazin and CLiK in the farm animal market.

### **Operating income**

Operating income rose 1% (+10% cc) to USD 209 million, with the operating income margin stable in the fourth quarter of 2010 at 12.8% of net sales. Currency effect reduced the reported operating profit by 9 percentage points due to the high concentration of production in Switzerland and South Asia. As in prior years, the margin reflects the typically higher advertising, promotional and trade spending behind seasonal brands mainly in the OTC business during the final quarter of the year.

The *Prevacid24HR* launch in the fourth quarter of 2009 has a significant effect on operating income comparisons for Consumer Health between the fourth quarters of 2009 and 2010.

Core operating income fell 4% (+3% cc) to USD 237 million, heavily impacted by the appreciation of the Swiss franc versus the prior year period. The core gross margin (67.7% of net sales, +1.6 percentage points) improved as a result of product mix and productivity gains. Marketing & Sales expenses (39.8% of net sales; -1.9 percentage points) increased to support marketing and sales investments. R&D (6.1% of net sales; +0.1 percentage points) continues to support new product development. Other Income and Expense (0.1% of net sales; -0.6 percentage points) declined due to a one-time benefit in the year-ago period.

#### Alcon, Inc.

	Q4 2010 USD m	FY 2010 USD m
Net sales	1 809	2 426
Operating income	222	323
As % of net sales	12.3	13.3
Core operating income	630	852
As % of net sales	34.8	35.1

On August 25, 2010, Novartis acquired an additional 52% of Alcon, Inc. (Alcon), raising its interest to a majority ownership of 77%, and thereafter consolidated Alcon s financial results. Prior to August 25, 2010, the Novartis share of Alcon s financial results was accounted in Income from associated companies.

Full year (Consolidated from August 25, 2010)

Net sales

Alcon s sales consolidated into Novartis Group results for the full year since August 25, 2010 totaled USD 2.4 billion. US sales of USD 1.0 billion accounted for 42% of total net sales, while non-US sales of USD 1.4 billion were 58% of total net sales. Sales in emerging markets continued to be strong, as they contributed USD 0.5 billion or 20% of total net sales. Pharmaceutical sales were USD 1.0 billion, Surgical sales were USD 1.1 billion and Consumer sales were USD 0.3 billion. Key product contributors to sales were the TRAVATAN® and Azopt® families of glaucoma products, Vigamox® for eye infections, Patanol® for eye allergies, AcrySof® intraocular lenses for cataract patients, and OPTI-FREE®, EXPRESS®, and Replenish® contact lens disinfecting solutions.

#### **Operating income**

Alcon has contributed USD 323 million to Novartis operating income since the consolidation of the controlling interest on August 25, 2010.

This amount includes an additional charge of USD 467 million relating to the estimated fair value revaluation of inventory as of the change in majority ownership date; USD 32 million for amortization of intangible assets; and USD 30 million of costs resulting from the change in majority ownership.

Excluding these items, Alcon s core operating income totaled USD 852 million.

### Fourth quarter

Net sales

Alcon s fourth quarter net sales were USD 1.8 billion. US sales of USD 0.8 billion accounted for 42% of total net sales, while non-US sales of USD 1.0 billion were 58% of total net sales. Alcon saw strong sales in emerging markets, which contributed USD 366 million or 20% of total net sales. Pharmaceutical sales were USD 740 million, Surgical sales were USD 858 million and Consumer sales were USD 211 million. Key products that contributed to these results were the TRAVATAN® ophthalmic solution and Azopt® ophthalmic suspension families of glaucoma products, Vigamox® ophthalmic solution for eye infections, Patanol® ophthalmic solution for eye allergies, AcrySof® intraocular lenses for cataract patients, and OPTI-FREE®, EXPRESS® and Replenish® multi-purpose contact lens disinfecting solutions.

#### **Operating income**

Alcon contributed USD 222 million to Novartis operating income.

This amount includes an additional charge of USD 372 million relating to the estimated fair value revaluation of inventory as of the change in majority ownership date; USD 25 million for amortization of intangible assets; and USD 11 million of costs resulting from the change in majority ownership.

Excluding these items, Alcon s core operating income totaled USD 630 million.

#### **FINANCIAL REVIEW**

### Fourth quarter and full year

	Q4 2010	Q4 2009	% cha	nge	FY 2010	FY 2009	% cha	nge
	USD m	USD m	USD	сс	USD m	USD m	USD	сс
Net sales	14 199	12 926	10	11	50 624	44 267	14	14
Divisional operating income	2 726	2 917	-7	-3	12 158	10 851	12	13
Corporate income & expense,								
net	-259	-280	-8	-10	-632	-869	27	30
Group operating income	2 467	2 637	-6	-3	11 526	9 982	15	17
as % of net sales	17.4	20.4			22.8	22.5		
Income from associated								
companies	175	107	64	62	804	293	174	173
Financial income	-26	104	nm	nm	64	198	-68	-68
Interest expense	-196	-156	26	25	-692	-551	26	25
Taxes	-155	-369	-58	-56	-1 733	-1 468	18	18
Net income	2 265	2 323	-2	2	9 969	8 454	18	20
EPS (USD)	0.95	1.01	-6	-2	4.28	3.70	16	17
Core operating income	3 166	3 204	-1	2	14 006	11 437	22	24
as % of net sales	22.3	24.8			27.7	25.8		
Core net income	2 803	2 892	-3	0	12 029	10 267	17	18
Core EPS (USD)	1.14	1.26	-10	-6	5.15	4.50	14	15

nm Not meaningful

### <u>Full year</u>

Net sales

Net sales rose 14% (+14% cc) to USD 50.6 billion driven by strong growth in all businesses, including USD 2.4 billion from the consolidation of Alcon. Recently launched products provided USD 10.4 billion of net

sales in the 2010 period, representing 21% of net sales compared to 16% in the 2009 period (excluding Alcon).

#### Corporate income & expense, net

Corporate income & expense includes the costs of Group headquarters and costs for corporate research. These net expenses of USD 632 million are 27% less than the prior year primarily due to the impact of an exceptional pension curtailment gain of USD 265 million arising from changing the conditions of the Swiss pension plan offset by USD 99 million of stamp duty and transaction expenses related to the acquisition of the additional 52% interest in Alcon.

Excluding these, corporate income & expense fell 8% compared to the prior year. From January 1, 2011, corporate research will be reported under the Pharmaceuticals Division. These research costs totaled USD 195 million in 2010.

#### Group operating income

Operating income rose 15% (+17% cc) to USD 11.5 billion on the volume-driven sales expansion. Unfavorable currency movements negatively impacted by two percentage points. The operating income margin improved 0.3 percentage points to 22.8% of net sales. One-off items arising in the year totaled a net USD 1.3 billion, comprising: impairments (USD 1.0 billion), legal settlements (USD 240 million), restructuring costs (USD 198 million), and Alcon-related costs (USD 596 million), offset by divestment and pension curtailment gains (USD 690 million). Core operating income grew 24% in constant currencies.

#### Income from associated companies

The income from associated companies for the full year 2010 increased from USD 293 million to USD 804 million. The increase is attributable to higher contributions from the Alcon and Roche investments due to exceptional charges incurred in the prior year period as well as the net revaluation gain to the estimated fair value of the initial 25% Alcon interest acquired on July 7, 2008 of USD 335 million. The following is a summary of the individual components included in the income from associated companies:

	Q4 2010 USD m	Q4 2009 USD m	FY 2010 USD m	FY 2009 USD m
Share of estimated Roche reported net income	168	132	648	593
Catch-up for actual Roche previous year net income				-40
Restructuring impact (2010 includes USD 43 million for				
2009)	-89		-132	-97
Amortization of intangible assets	-35	-37	-136	-135
Net income effect from Roche	44	95	380	321
Share of Alcon, Inc. reported net income		125	385	493
Catch-up for actual Alcon previous year net income			2	5
Revaluation of initial 25% interest to deemed fair value	174		378	
	-43		-43	

Recycling of losses accumulated in comprehensive income				
from July 7, 2008 to August 25, 2010				
Intangible asset impairment charge				-92
Amortization of intangible assets		-108	-289	-434
Net income effect from Alcon (in 2010 up to August 25,				
2010)	131	17	433	-28
Net income from other associated companies		-5	-9	
Income from associated companies	175	107	804	293

Core results for associated companies, excluding the exceptional charges due to the Genentech restructuring for Roche and the intangible asset impairment charge and revaluation gain for Alcon as well as the amortization of intangible assets for both investments, decreased slightly by USD 10 million over the year.

### Financial income and interest expense

Financial income decreased by 68% from USD 198 million to USD 64 million. Interest expense increased by 26% to USD 692 million from USD 551 million in the prior year period as a result of the issuance of US dollar bonds in February 2009 and March 2010, a euro bond in June 2009 and the increase of short-term debts through the commercial paper program.

### Taxes

The tax rate (taxes as percentage of pre-tax income) remained unchanged compared to the prior year at 14.8%.

Excluding the impact of consolidating Alcon, the Group s full year tax rate would have been 16.3%, which is higher than 2009 as it reflects the impact of sales from A(H1N1) pandemic flu vaccines and other sales being recorded in higher tax jurisdictions.

#### Net income

Net income advanced 18% (+20% cc) to USD 10.0 billion ahead of operating income growth. Core net income grew 17% (+18% cc) to USD 12.0 billion.

### Earnings per share

Earnings per share (EPS) rose 16% (+17% cc) to USD 4.28 from USD 3.70 in 2009, while core EPS grew 14% (+15% cc) to USD 5.15 from USD 4.50. The average number of shares outstanding in 2010 rose 1% to 2,285.7 million from 2,267.9 million in the year-ago period, while a total of 2,289.4 million shares were outstanding at December 31, 2010.

#### **Balance sheet**

The full consolidation of Alcon has had a significant impact on the Group s consolidated balance sheet. Non-current assets have increased by USD 34.8 billion since December 31, 2009, of which the major items resulted from the consolidation of Alcon from August 25 and the related purchase price allocation, which increased identified intangible assets by USD 24.5 billion and goodwill by USD 17.9 billion. Furthermore, this also reduced the amount of investments in associated companies (included in financial and other non-current assets) by USD 10.0 billion. Current assets decreased by USD 7.0 billion mainly due to USD 9.3 billion lower cash and marketable securities as these funds were used to acquire the additional 52% interest in Alcon. Trade accounts receivable, inventories and other current assets increased by USD 2.3 billion also mainly due to the consolidation of Alcon. As a result of the consolidation of Alcon and other factors, total assets amounted to USD 123.3 billion at December 31, 2010, an increase of USD 27.8 billion compared to the end of 2009.

Similarly, the consolidation of Alcon and related financing for the additional 52% interest has had a significant impact on the Group s liabilities and equity. Financial debts increased by USD 9.0 billion. A portion of this was used to fund the Alcon acquisition. In addition, we raised funds through our commercial paper program, the proceeds from which were used for general corporate purposes of the Novartis Group, as well as for intercompany financing purposes in connection with the acquisition of the 52% interest in Alcon. Other current and non-current liabilities increased by USD 6.5 billion of which USD 3.3 billion are additional deferred tax liabilities primarily related to the Alcon identified intangible assets. Principally due to these factors, total liabilities increased by USD 15.5 billion to USD 53.5 billion at December 31, 2010. The Group s equity rose by USD 12.3 billion since the prior year-end to USD 69.8 billion at December 31, 2010, which includes the net income of USD 10.0 billion as well as an additional USD 6.3 billion related to the 23% non-controlling interests in Alcon, Inc. and USD 0.9 billion from net sales of

treasury shares and share-based compensation as well as favorable currency translation effects which contributed USD 0.6 billion. This increase was partially offset by the dividend payment for 2009 of USD 4.5 billion and actuarial losses of USD 0.7 billion, and net movements related to non-controlling interests and associated companies of USD 0.3 billion.

The Group s debt/equity ratio rose to 0.33:1 at December 31, 2010, compared to 0.24:1 at the end of 2009, reflecting the higher financial debt for the funding of the Alcon acquisition. The Group s financial debt of USD 23.0 billion consisted of USD 8.6 billion in current and USD 14.4 billion in non-current liabilities. Overall liquidity, including USD 3.8 billion consolidated with Alcon, decreased to USD 8.1 billion from USD 17.4 billion at the end of 2009. Net debt at December 31, 2010 was USD 14.9 billion compared to net liquidity of USD 3.5 billion at the end of the previous year.

### Cash flow

Cash flow from operating activities was USD 14.1 billion in 2010, a 15.4% increase from USD 12.2 billion in 2009. The additional cash flow of USD 1.9 billion generated by the strong business expansion and lower working capital requirements was partially offset by higher taxes and payments in connection with the resolution of certain legal matters.

The net cash outflow used for investing activities in 2010 amounted to USD 15.8 billion, USD 1.5 billion above the prior-year amount. The cash used for acquisition was USD 26.7 billion. This amount is comprised

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of USD 26.1 billion (net of USD 2.2 billion cash acquired) for the purchase of the additional 52% investment in Alcon and of USD 0.5 billion for the acquisition of Corthera and Oriel, as well as for deferred payments related to the EBEWE acquisition. The net cash used for investments in property, plant & equipment, intangible and other assets amounted to USD 1.7 billion. These outflows were partially offset by the net proceeds of marketable securities of USD 12.6 billon.

Net cash provided by financing activities increased by USD 1.3 billion to USD 4.1 billion in 2010 compared to USD 2.8 billion in 2009. The USD 8.3 billion proceeds from the bonds and commercial paper programs as well as other net inflows totaling USD 0.3 billion were partially offset by the payment of the 2009 dividend of USD 4.5 billion in 2010.

Free cash flow for 2010 was USD 7.9 billion, which represents an increase of 42.8% over 2009. Free cash flow before dividends for 2010 was USD 12.3 billion, an increase of 31% compared to 2009.

### Fourth quarter

#### Net sales

Net sales rose 10% (+11% cc) to USD 14.2 billion. Alcon sales were USD 1.8 billion for the quarter. Unfavorable currency movements depressed the result by 1 percentage point (excluding Alcon). Recently launched products provided USD 2.5 billion of net sales, which represent 20% of total sales (excluding Alcon).

### Corporate income & expense, net

Corporate income & expense, which includes the costs of the Group headquarters and costs for corporate research, was USD 21 million less in the fourth quarter compared to the prior year, principally due to higher pension income.

#### Group operating income

Operating income decreased 6% (-3% cc). Currency had a negative impact of 3 percentage points. Alcon contributed operating income of USD 222 million. One-off items in the quarter included charges totaling USD 789 million, partially offset by a gain of USD 392 million from the divestment of *Enablex*. These charges include Pharmaceuticals USD 253 million (mainly ASA404 impairment USD 120 million and US restructuring costs USD 85 million), Sandoz USD 49 million (German restructuring), Vaccines and Diagnostics USD 75 million (manufacturing restructuring USD 52 million and financial asset impairment USD 23 million), and Alcon USD 383 million (fair value revaluation of inventory USD 372 million and costs resulting from the change in majority ownership USD 11 million). Core operating income was unchanged in constant currencies at USD 2.8 billion.

### Income from associated companies

The income from associated companies in the fourth quarter of 2010 increased to USD 175 million from USD 107 million in 2009. Alcon, Inc., accounted for as an associated company until August 25, 2010, and thereafter fully consolidated. A final revaluation of the initial 25% interest in Alcon in the quarter contributed a net of USD 131 million. 2009 included amortization charges of USD 108 million. The Roche investment contributed USD 44 million in the fourth quarter including an estimated charge of USD 89 million for the Novartis share of the recently announced Roche restructuring.

Core results for associated companies for the fourth quarter, which exclude exceptional items and the amortization of intangible assets in both periods, decreased from USD 252 million in the 2009 fourth quarter to USD 168 million in the current year quarter.

#### Financial income and interest expense

Financial income decreased from USD 104 million income in the fourth quarter of 2009 to net financial expense of USD 26 million in the current fourth quarter due to lower returns on financial investments and a negative currency result, mainly attributable to a devaluation loss in Venezuela. Interest expense increased from USD 156 million to USD 196 million due to the additional fund-raising in relation to Alcon.

#### Taxes

The tax rate (taxes as a percentage of pre-tax income) was an exceptionally low 6.4% in the fourth quarter compared to 13.7% in the 2009 period, principally due to the true up of the Novartis tax rate to 16.3% and the impact of the consolidation of Alcon, which has a lower tax rate than the rest of the Novartis Group, and the deferred tax effects of the Alcon inventory-related fair value adjustment.

#### Net income

Net income declined 2% (+2% cc) to USD 2.3 billion. Core net income declined 3% (0% cc) to USD 2.8 billion.

#### Earnings per share

Earnings per share (EPS) declined 6% (-2% cc) to USD 0.95 from USD 1.01 in the 2009 period and core EPS was down 10% (-6% cc) to USD 1.14 from USD 1.26 in the year-ago period. The decrease in EPS is greater than the decrease in net income because 23% of the net income of Alcon is related to Alcon non-controlling interests and therefore excluded from the EPS calculation.

The average number of shares outstanding in the fourth quarter rose 1% to 2,289.8 million from 2,272.8 million in the year-ago period while a total of 2,289.4 million shares were outstanding at December 31, 2010.

### **INNOVATION REVIEW**

Novartis has one of the industry s most competitive pipelines with 147 projects in pharmaceutical clinical development, of which 63 involve new molecular entities.

Among developments in the fourth quarter of 2010:

• The FDA approved *Afinitor* (everolimus) tablets for subependymal giant cell astrocytoma, a benign brain tumor associated with tuberous sclerosis, in patients who require therapeutic intervention but are not candidates for curative surgical resection. The regulatory submission in the EU is currently under review with the trade name *Votubia*. Separately, we have filed *Afinitor* for the treatment of patients with advanced neuroendocrine tumors in the US and EU.

• The FDA approved *Amturnide* (aliskiren, amlodipine and hydrochlorothiazide) tablets, a triple-combination pill for the treatment of hypertension in patients whose blood pressure cannot be adequately controlled with any two of its individual components. Clinical trial data showed that *Amturnide* provided significantly greater reduction in blood pressure compared to all dual combinations of its components.

• In December, the EMA and Japan s Ministry of Health, Labour and Welfare granted marketing authorization to *Tasigna* (nilotinib) for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. *Tasigna* was approved for this indication earlier in 2010 in the US and Switzerland.

• In January 2011, the European Commission approved *Lucentis* (ranibizumab) for the treatment of patients with visual impairment due to diabetic macular edema, a leading cause of blindness in the working-age population in most developed countries. Data from pivotal trials had shown that *Lucentis* is superior to laser therapy, the current standard of care, in providing rapid and sustained visual acuity gain.

• In January 2011, the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for *Gilenya* (fingolimod) 0.5 mg daily as a disease modifying therapy in patients with highly active relapsing-remitting multiple sclerosis (MS) despite treatment with beta interferon, or in patients with rapidly evolving severe relapsing-remitting MS. The EU application included data showing *Gilenya* 0.5 mg reduced relapses by 52% (P<0.001) at one year compared with interferon beta-1a IM (Avonex®), one of the most commonly prescribed treatments for MS.

• *Lucentis* was submitted in October for EU approval to treat visual impairment due to macular edema secondary to retinal vein occlusion (RVO). The filing is based on results from two separate Phase III studies in central RVO and branch RVO (CRUISE and BRAVO, both conducted by our licensing partner Genentech) in which *Lucentis* showed significant improvement versus sham injection at 6 and 12 months of treatment.

• In December, Novartis filed for European regulatory approval of ACZ885 (*Ilaris*, canakinumab) for the treatment of gouty arthritis based on data from two Phase III registration studies that met their primary endpoints. US submission is on track for the first quarter of 2011. Novartis is also pursuing other diseases in which IL-1 is believed to play an important role, such as systemic juvenile idiopathic

arthritis and cardiovascular indications. Select subsets of patients with these diseases would be eligible for treatment with canakinumab, if approved.

• A dossier for EU approval of SOM230 (pasireotide) in patients suffering from Cushing s disease was filed in December. In a Phase III trial, SOM230 demonstrated significant efficacy in reducing urinary and free cortisol levels in patients suffering from this debilitating and potentially fatal hormonal disorder.

• The Phase III COMFORT-I trial met its primary endpoint demonstrating that INC424 significantly reduced spleen size in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. Full results from the trial will be presented at an upcoming medical congress and worldwide regulatory filings are planned for 2011. Novartis licensed INC424 from Incyte for development and potential commercialization outside the US.

• Results from a blinded Phase III head-to-head study (INTENSITY) comparing once-daily *Onbrez Breezhaler* with tiotropium, an established therapy for chronic obstructive pulmonary disease (COPD), showed that *Onbrez Breezhaler* is as effective as tiotropium in improving lung function in patients with COPD, while providing greater clinical benefits in terms of reduced breathlessness, lower use of rescue medication, and improved overall health status. While the trial met its primary endpoint and these secondary endpoints relating to key patient outcomes, it did not meet the secondary endpoint of superiority to tiotropium in terms of lung function.

• The interim results from a Phase III trial examining ASA404 (valdimezan) for second line treatment of non-small cell lung cancer failed to meet the primary endpoint of extending survival in these patients. The project was discontinued and resources were reallocated to other compounds in the Oncology pipeline.

• At the San Antonio Breast Cancer Symposium, results were presented from the second interim analysis of the Phase III AZURE trial, which showed that *Zometa* did not demonstrate a disease-free survival advantage when added to standard adjuvant (post-surgery) chemotherapy and/or hormonal therapy in pre- and postmenopausal women with early breast cancer. However, a preplanned analysis of women with well-established menopause showed an improvement in disease-free survival and overall survival for patients in the *Zometa* treatment arm. Current applications in the US and EU for adjuvant treatment in early breast cancer have been withdrawn and Novartis will evaluate future plans based on these new data after discussions with health authorities worldwide.

• Novartis did not proceed with the US submission for everolimus in heart transplant. The results of the latest heart transplant phase III study are consistent with a safe and effective use of everolimus when administered according to approved labels in those countries where everolimus is registered for heart transplantation. Results associated with additional investigational use of everolimus are planned to be discussed with the FDA.

### Q4 2010 selected major approvals: US, Europe and Japan

Product	Active ingredient	Indication	Approval date
Afinitor	everolimus		US-October

		Subependymal giant cell	
		astrocytomas associated with	
		tuberous sclerosis	
Amturnide	aliskiren, amlodipine and hydrochlorothiazide	Hypertension	US-December
Lucentis	ranibizumab	Diabetic macular edema	EU January 2011
Tasigna	nilotinib	Newly diagnosed chronic myeloid leukemia	EU-December
			Japan-December

### Selected projects awaiting regulatory decisions

			Completed submissions		
Product	Indication	US	EU	Japan	News update
ACZ885	Gouty arthritis		Q4 2010		- EU filing achieved in December
					- US submission planned in Q1 2011
Afinitor	Subependymal giant cell astrocytomas	Approved	Q3 2010		- FDA approval received in October
					- Phase II data published in <i>New England Journal of Medicine</i> in

	associated with tuberous sclerosis Neuroendocrine tumors		Q4 2010	Q4 2010	November - US, EU and Japan filing completed
Exelon Patch	Alzheimer s disease dementia	Approved	Approved	Q1 2010	- New drug application in Japan is under review. Pharmaceuticals and Medical Devices Agency decision expected in coming months

			Completed submissions	_	
Product Cilama	Indication	US	EU Q4 2009	<b>Japan</b> Q4 2010	News update
Gilenya	Multiple sclerosis	Approved	Q4 2009	Q4 2010	- FDA approval received in September with first-line indication for relapsing forms of multiple sclerosis. Additional approvals received in Russia, Switzerland, Australia and the United Arab Emirates
					- In January 2011, we received positive CHMP opinion for use in patients with highly active relapsing-remitting multiple sclerosis (MS) despite treatment with beta interferon, or in patients with rapidly evolving severe
					relapsing-remitting MS
LBH589	Hodgkin s lymphoma	Q4 2010			- US filing achieved in December
					- Phase II pivotal study data presented at the American Society of Hematology in December
Lucentis	Retinal vein occlusion		Q4 2010		- EU filing achieved in October
Onbrez Breezhaler	Chronic obstructive pulmonary disease	Q4 2008	Approved	Q3 2010	- Clinical trials completed in Q3 2010 to address FDA complete response letter (October 2009); data generated from these trials were submitted to the FDA in late September
					- The application for US approval (under the trade name <i>Arcapta Neohaler</i> ) is due to be reviewed by an FDA Advisory Committee in March 2011
SOM230	Cushing s disease		Q4 2010		- EU filing achieved in October
					- US filing expected in H1 2011
Tekamlo	Hypertension	Approved	Q4 2009		- FDA approval received in August
					- EU CHMP opinion expected in Q1 2011
Amturnide	Hypertension	Approved	Q2 2010		- FDA approval received in December
					- EU submission achieved in May 2010
TOBI Podhaler	Cystic fibrosis		Q4 2009		- Positive CHMP opinion received in September
Zometa	Adjuvant breast cancer	Q4 2009	Q4 2009		- Phase III AZURE trial of <i>Zometa</i> for potential new use in early breast cancer did not meet primary endpoint in overall study population. In subgroup of women with well-established menopause, an improvement in disease-free survival and overall survival was shown in <i>Zometa</i> arm
					- Current marketing applications have been withdrawn in the US and EU while Novartis reviews AZURE trial results

- Novartis will discuss with health authorities the next steps based on the subgroup analysis

### Selected pharmaceutical pipeline projects

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
ACZ885	Systemic onset juvenile idiopathic arthritis	2011	III	- On track for 2011 submission
	Secondary prevention of cardiovascular events	<u>≥</u> 2015	II	- Phase III start planned in 2011
	Type 2 diabetes	<u>≥</u> 2015		
AEB071	Prevention of organ rejection	2014	II	
	Psoriasis	<u>≥</u> 2015	II	
Afinitor	Tuberous sclerosis complex angiomyolipoma	2011	III	
	ER+ breast cancer	2012	III	- Phase II TAM-RAD trial evaluating the effect of the addition of everolimus ( <i>Afinitor</i> ) to the hormonal therapy tamoxifen in patients with advanced metastatic breast cancer presented at San Antonio Breast Cancer Symposium in December
	HER2+ breast cancer 1st line	2013	III	
	HER 2+ve breast cancer 2nd/3rd line	2013	III	
	Advanced gastric cancer	2012	III	
	Hepatocellular cancer	2013	III	
	Diffuse large B cell lymphoma	<u>≥</u> 2015	III	
AFQ056	Fragile X syndrome	2012	II	- Adult pivotal study started in November 2010
	Parkinson s disease- L-dopa induced dyskinesia	2013	II	
AG0178	Major depressive disorder	2012	III	
AIN457	Psoriasis	2013	II	
	Rheumatoid arthritis Non-infectious uveitis	2013 2013	II III	<ul> <li>Phase III start planned for 2011</li> <li>Phase III study examining AIN457 for non-infectious uveitis in patients with Behcet s disease did not meet its primary endpoint and the data do not support submission of AIN457 for this indication</li> </ul>
BAF312	Multiple sclerosis	<u>≥</u> 2015	II	- Phase II data expected in Q1 2011
BEZ235	Solid tumors	2014	Ι	
BKM120	Solid tumors	2014	Ι	
CAD106	Alzheimer s disease	<u>≥</u> 2015	II	
DEB025	Hepatitis C	2013	Π	<ul> <li>Following a positive End-of-Phase II meeting with the FDA and positive feedback from the EMA, both endorsing the Phase III program, the Phase III clinical trial with DEB025 (<i>Alisporivir</i>) is planned to start in Q1 2011</li> <li>This study will investigate DEB025 in combination with peg-interferon and</li> </ul>
		2011	H	ribavirin in HCV G1 treatment-naive patients
Exjade	Non-transfusion-dependent thalassemia	2011	II	
HCD122	Hematological tumors	<u>≥</u> 2015	Ι	

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
INC424	Myelofibrosis Polycythemia vera	2011 2014	III	<ul> <li>Phase III COMFORT-I trial top-line results show study met primary endpoint; INC424 provided significant clinical improvement in patients with myelofibrosis as measured by spleen size reduction. Full results to be presented at major medical congress in 2011</li> <li>First interpretable results (FIR) of Phase III COMFORT-2 data expected in Q1 2011</li> <li>First US patient dosed in global Phase III RESPONSE study; first ex-US patient study expected to start in Q1 2011</li> <li>Phase II data in PV presented at the American Society of Hematology in</li> </ul>
LBH589	Multiple myeloma	2013	III	December
LDII509	Hematological tumors	≥2015	II	
LCQ908	Metabolic diseases	2014	II	
LCZ696	Heart failure	2014	Ш	<ul> <li>Phase II data published in <i>Lancet</i> and presented at the American College of Cardiology in March 2010. The study demonstrated blood pressure lowering and supports heart failure potential</li> <li>Phase III morbidity and mortality study in the staff.</li> </ul>
	Unertension	2014	II	heart failure ongoing since December 2009
LDE225	Hypertension Gorlin s syndrome	2014 2012	II	
	Solid tumors	2012	I	
Lucentis	Pathological myopia	2012	III	- Phase III started in Oct 2010
NVA237	Chronic obstructive pulmonary disease	2011	III	<ul> <li>On track for 2011 submission</li> <li>Phase III (Glow 1,Glow 2 and Glow 3) data expected in 2011</li> </ul>
PKC412	Aggressive systemic mastocytosis	2013	II	
	Acute myeloid leukemia	2014	III	
PRT128	Acute coronary syndrome, chronic coronary heart disease	<u>≥</u> 2015	П	- Results from INNOVATE-PCI Phase II study were presented at the European Society of Cardiology congress in August 2010
				- Phase III clinical development program to be initiated in 2011
РТК796	Acute bacterial skin and skin structure infections, community-acquired bacterial pneumonia	2012	III	
QGE031	Allergic diseases	2014	Ι	
QMF149	Chronic obstructive pulmonary disease	2014	Π	- Currently in Phase II with filing in ex-US regions planned for 2014

- At this time we do not intend to develop QMF149 for the US market

	Asthma	2014	Π	- Filing in EU planned for 2014
				- US development activities will not be initiated
QTI571 (Imatinib)	Pulmonary arterial hypertension	2011	III	- On track for 2011 submission
				- Data expected in H2 2011
QVA149	Chronic obstructive pulmonary disease	2012	III	

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
RLX030	Acute heart failure	2013	III	
SMC021	Osteoporosis	2011 2011	III	<ul> <li>First Phase III study did not meet first of three co-primary endpoints; second Phase III study ongoing</li> <li>Phase III pivotal study (Study 2303) is continuing following the two-year interim analysis in Q4 2010. Three-year results are expected in Q3 2011</li> </ul>
SOM230	Acromegaly	2011		-