

NOVARTIS AG  
Form 6-K  
January 25, 2012

# 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 25th 2012**

**(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:

Edgar Filing: NOVARTIS AG - Form 6-K

**Form 20-F:**  **Form 40-F:**

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:  No:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  No:

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:  No:

---

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

**FINANCIAL REPORT • RAPPORT FINANCIER • FINANZBERICHT**

**Novartis delivers strong underlying financial performance in 2011, expects 2012 sales to be in line with 2011**

- **Fourth quarter sales rose 5% while core(1) operating income grew 17% in constant currencies (cc); full year sales up 12% cc and core operating income up 16% cc**
- **Net sales increased 4% (+5% cc) to USD 14.8 billion; full year up 16% (+12% cc) to USD 58.6 billion**
- **Core operating income grew 12% (+17% cc) to USD 3.6 billion in the fourth quarter; full year up 14% (+16% cc) to USD 15.9 billion; core margin of 24.0% up 2.7 percentage points in cc; full year core margin of 27.2% up 1.1 percentage points in cc**
- **Core EPS advanced 8% to USD 1.23 (+13% cc) from USD 1.14 in the previous-year quarter; full year core EPS up by 8% (+11% cc) to USD 5.57**
- **Operating income declined 47% (-38% cc) in the quarter and 5% (+1% cc) for the full year, driven by fourth quarter net exceptional charges totaling USD 1.5 billion; EPS declined 48% (-40% cc) in the quarter and 11% (-5% cc) for the full year**
- **Free cash flow of USD 3.9 billion; full year free cash flow of USD 12.5 billion**
- **Dividend of CHF 2.25 per share proposed for 2011; 15th consecutive increase**
- **Diversified healthcare portfolio and industry-leading pipeline expected to enhance our ability to sustain growth through patent expirations**

## Edgar Filing: NOVARTIS AG - Form 6-K

- **Alcon, world leader in eye care, fully integrated** as second largest division in Novartis Group portfolio
  
- Portfolio rejuvenation continues to gain momentum with **Group recently launched products growing 38% and contributing 25% (USD 14.4 billion) of 2011 net sales**
  
- Strong Pharmaceuticals pipeline results with **15 approvals in the US, EU and Japan in 2011**; worldwide filings underway for *Afinitor* in breast cancer
  
- **Outlook 2012:** Novartis expects sales to be in line with 2011 despite *Diovan* patent expiry and *Tektural/Rasilez* decline; core operating income margin (cc) expected to be slightly below 2011

### Key figures

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>14 781</b>	14 199	4	5	<b>58 566</b>	50 624	16	12
<b>Operating income</b>	<b>1 317</b>	2 467	-47	-38	<b>10 998</b>	11 526	-5	1
<b>Net income</b>	<b>1 210</b>	2 265	-47	-37	<b>9 245</b>	9 969	-7	-2
<b>EPS (USD)</b>	<b>0.49</b>	0.95	-48	-40	<b>3.83</b>	4.28	-11	-5
<b>Free cash flow</b>	<b>3 909</b>	4 180	-6		<b>12 503</b>	12 346	1	
<b>Core(1)</b>								
<b>Operating income</b>	<b>3 550</b>	3 166	12	17	<b>15 909</b>	14 006	14	16
<b>Net income</b>	<b>3 011</b>	2 803	7	12	<b>13 490</b>	12 029	12	15
<b>EPS (USD)</b>	<b>1.23</b>	1.14	8	13	<b>5.57</b>	5.15	8	11

(1) See page 52 for further information and definition of core results

All product names appearing in italics are trademarks owned by or licensed to Novartis Group Companies.

**Basel, January 25, 2012** Commenting on the results, Joseph Jimenez, CEO of Novartis, said:

*Novartis achieved solid sales growth and strong operating leverage in the fourth quarter and for the year as a whole. We maintained our innovation momentum this year, achieving 15 key approvals and expanding our already robust pipeline. We also improved core margins through targeted productivity initiatives. However, we experienced some disappointments in the fourth quarter, with Tekturna/Rasilez and with the need to improve our quality standards at some manufacturing sites. We are committed to ensuring one single high quality standard across Novartis and will invest the necessary resources to achieve this goal in all divisions. Novartis is well positioned as we face the expected patent expirations and will continue discovering new treatments to improve the health of patients across the globe.*

## **GROUP REVIEW**

### **Fourth quarter**

#### **Strong net sales growth driven by recently launched products**

Net sales rose 4% (+5% cc) to USD 14.8 billion in the fourth quarter. The strengthening of the US dollar against most major currencies negatively impacted sales by 1 percentage point.

Our portfolio rejuvenation continued to drive overall growth for the Group, as recently launched products sales grew 30% (USD) over the previous-year quarter to USD 3.7 billion. These products contributed 25% (USD) of Group net sales, up from 20% in the year-ago period.

Pharmaceuticals net sales grew 4% (+5% cc) to USD 8.3 billion, driven by 10 percentage points of volume growth, partly offset by generic entries and product divestments, which had a negative impact of 5 percentage points. Alcon net sales of USD 2.4 billion rose 6% (+7% cc) on a pro forma basis, while Sandoz net sales declined 5% (-4% cc) to USD 2.3 billion due to additional competition to enoxaparin. Vaccines and Diagnostics net sales expanded 86% (+86% cc) to USD 671 million. Consumer Health which comprises OTC and Animal Health was down 7% (-6% cc) at USD 1.1 billion due to OTC product return provisions, following the temporary suspension of production at one of the US Consumer Health sites.

Operating income was down 47% (-38% cc) to USD 1.3 billion. Exceptional income and expense in the fourth quarter amounted to a net USD 1.5 billion expense compared to USD 397 million expense in the prior year. The strengthening of the US dollar, combined with the already strong Swiss franc, resulted in a negative currency impact of 9 percentage points.

The net exceptional charge of USD 1.5 billion (2010 USD 397 million) comprised charges of USD 1.7 billion (2010 USD 789 million) offset by exceptional income of USD 186 million (2010 USD 392 million mainly related to the Enablex® divestment). Exceptional charges included: USD 903 million for *Tekturna/Rasilez*, USD 163 million related to the discontinuation of the PRT128 (elinogrel) and SMC021 (oral calcitonin) development programs, a charge of USD 115 million related to the temporary suspension of production at one of our US Consumer Health sites,

## Edgar Filing: NOVARTIS AG - Form 6-K

Alcon integration charges of USD 61 million, and restructuring costs of USD 288 million. Exceptional income includes a USD 106 million reduction of a contingent consideration obligation in Sandoz. Amortization of intangible assets amounted to USD 742 million compared to USD 302 million in 2010 mainly as a result of the Alcon acquisition.

### **Core operating income grew strongly ahead of sales**

Core operating income, which excludes the exceptional items identified above together with amortization of intangible assets, increased by 12% (+17% cc) to USD 3.6 billion. Core operating income margin in constant currencies increased by 2.7 percentage points. However, this improvement was offset by a negative currency impact of 1.0 percentage point, resulting in a net increase in core operating income margin of 1.7 percentage points to 24.0% of net sales.

Net income decreased 47% (-37% cc), in line with the decline in operating income. EPS declined 48% (-40% cc) at a slightly higher rate than net income as a result of the increase in issued shares following the Alcon merger, partially offset by a lower impact from non-controlling interests.

Core net income grew 7% (+12% cc) below the rate of growth of core operating income as a result of a higher core tax charge (15% compared to 10% in the prior year). Core EPS was up by 8% (+13% cc).

Free cash flow of USD 3.9 billion was 6% lower than in the previous-year quarter mainly as a result of the Enablex® divestment proceeds of USD 392 million in the fourth quarter of 2010.

## **Full year**

### **Double-digit net sales growth**

Net sales rose 16% (+12% cc) to USD 58.6 billion, with a positive currency impact of 4% arising from the weakness of the US dollar against most major currencies during much of 2011.

Recently launched products sales grew 38% over 2010 (in USD, excluding the A(H1N1) pandemic flu vaccine and including Alcon on a pro forma basis for 2010) to USD 14.4 billion. These products contributed 25% of Group net sales, up from 19% in 2010.

Pharmaceuticals net sales grew 7% (+4% cc) to USD 32.5 billion, and Alcon net sales of USD 10.0 billion rose 10% (+7% cc) on a pro forma basis. Sandoz net sales also grew 10% (+7% cc) to USD 9.5 billion. Vaccines and Diagnostics net sales were down 32% (-34% cc) to USD 2.0 billion, mainly due to USD 1.3 billion of A(H1N1) pandemic flu vaccine sales in 2010. Net sales of the two Consumer Health businesses together grew 6% (+3% cc) to USD 4.6 billion.

Operating income was down 5% (+1% cc) to USD 11.0 billion. Exceptional income and expense in 2011 amounted to a net USD 1.9 billion expense compared to USD 1.3 billion expense in the prior year. The weakness of the US dollar, combined with the strong Swiss franc, resulted in a negative currency impact of 6 percentage points.

The net exceptional charge of USD 1.9 billion (2010 USD 1.3 billion) comprised charges of USD 2.9 billion (2010 USD 2.1 billion) offset by exceptional income of USD 1.0 billion (2010 USD 732 million). Exceptional charges included: charges for *Tektural/Rasilez* (USD 903 million), USD 348 million related to the discontinuation of the PRT128 (elinogrel), SMC021 (oral calcitonin), AGO178 (agomelatine), and PTK796 development programs, a charge of USD 115 million related to the temporary suspension of production at one of our US Consumer Health sites, other intangible asset impairment charges of USD 71 million principally relating to development projects, financial asset impairment charges of USD 192 million, integration charges of USD 250 million (mainly for Alcon), and restructuring and related costs of USD 492 million. Exceptional income includes divestment proceeds (USD 480 million) and a USD 106 million reduction of a contingent consideration obligation in Sandoz. For the full year, amortization of intangible assets amounted to USD 3.0 billion compared to USD 1.1 billion in 2010 as a result of a full year of incorporating Alcon.

### **Constant currency core margin up 1.1 percentage points**

As a result, core operating income, which excludes the exceptional items identified above together with amortization of intangible assets, increased 14% (+16% cc) to USD 15.9 billion. Core operating income margin in constant currencies increased by 1.1 percentage points.

## Edgar Filing: NOVARTIS AG - Form 6-K

However, this improvement was offset by a negative currency impact of 1.6 percentage points, resulting in a net decrease in core operating income margin of 0.5 percentage points to 27.2% of net sales.

Net income decreased 7% (-2% cc) to USD 9.2 billion, more than the decline in operating income as a result of lower associated company income, higher financing costs following the Alcon acquisition, partly offset by a lower tax rate (14.2% compared to 14.8%). EPS declined 11% (-5% cc), more than the decline in net income, mainly as a result of the increase in issued shares following the Alcon merger, partially offset by a lower impact from non-controlling interests.

Core net income grew 12% (+15% cc) to USD 13.5 billion broadly in line with core operating income. Core EPS was up by 8% (+11% cc): a lower rate than net income as a result of a higher number of outstanding shares in 2011.

Free cash flow reached USD 12.5 billion (2010 USD 12.3 billion), an increase of 1% over the previous year. Free cash flow in 2010 included substantial cash flows from sales of A(H1N1) amounting to USD 1.8 billion.



**Delivering against strategic priorities of innovation, growth and productivity**

The Novartis strategy for sustained, long-term growth is based on advancing science to meet global patient needs across the healthcare spectrum and is underpinned by a consistent focus on three key priorities: innovation, growth and productivity. On all of these fronts, Novartis made significant progress in 2011, and the key developments in the fourth quarter are listed below.

**Innovation: Bringing new innovative medicines to patients**

Scientific innovation is at the heart of the Novartis strategy. We plan to maintain our industry-leading commitment to R&D, which we expect will allow us to discover and develop new targeted therapies for patients worldwide. Our track record of innovation excellence, which has produced one of the most productive pipelines in the global pharmaceutical industry, is expected to help us maintain growth momentum despite the anticipated loss of revenues from patent expirations.

**Regulatory filings underway for *Afinitor* in breast cancer**

In the fourth quarter, we filed applications worldwide for approval of *Afinitor* (everolimus) in advanced ER+/HER2- breast cancer, potentially representing the first major breakthrough in the treatment of this disease in 15 years. The filing was based on updated data from a Phase III trial (BOLERO-2) of everolimus in combination with exemestane for postmenopausal women with advanced breast cancer that recurred or progressed despite treatment with hormonal therapies. If approved, this indication for everolimus which is already approved for the treatment of advanced kidney cancer, advanced pancreatic neuroendocrine tumors and subependymal giant cell astrocytomas associated with tuberous sclerosis complex, as well as other non-oncology indications would further validate the Novartis research strategy, which is based on understanding the molecular pathways of diseases.

A separate Phase III study (GRANITE-1) of everolimus in patients with advanced gastric cancer did not meet its primary endpoint, with everolimus plus best supportive care (BSC) failing to show a statistically significant difference over placebo plus BSC in overall survival.

**ACZ885 Phase III study showed promise for treatment of childhood arthritis**

A study of ACZ885 showed that 45% of children with active systemic juvenile idiopathic arthritis (SJIA) were able to substantially reduce their use of steroids within 28 weeks of commencing treatment with ACZ885. The study also showed SJIA patients treated with ACZ885 were nearly three times less likely to suffer a new flare versus placebo. A subtype of the more common juvenile idiopathic arthritis, SJIA is the most serious form of childhood arthritis, and the positive results of this study represent another success in the Novartis commitment to finding new treatments wherever there is patient need.

**Two Phase III studies continued to show superiority of *Tasigna* over *Glivec***

Data from two studies (ENESTcmr and ENESTnd) contributed to the growing body of evidence indicating that adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) who are treated with *Tasigna* have a better response at the molecular level than those treated with *Glivec*, the long-time standard of care.

**Updated positive Phase III results of INC424 in myelofibrosis**

Two pivotal Phase III trials (COMFORT-I and -II) demonstrated the significant potential of Janus kinase inhibitor INC424 in treating patients with myelofibrosis, a life-threatening blood cancer. COMFORT-II data showed that INC424 provided improvements in symptoms at each evaluation versus the best available therapy, underlining the dramatic benefits that INC424 can have on quality of life for patients suffering from this debilitating disease. In addition, in the COMFORT-I survival analysis, INC424 demonstrated an early overall survival advantage over placebo.

***Gilenya* continued to demonstrate efficacy in large-scale clinical trials; FDA and EMA review of benefits and risks**

Now supported by more than 25,000 patients on drug, *Gilenya*, our breakthrough oral multiple sclerosis (MS) treatment, continues to demonstrate efficacy in Phase III studies. In the fourth quarter, new data from the FREEDOMS II trial showed patients with relapsing-remitting multiple sclerosis treated with *Gilenya* experienced a 48% reduction in relapse rates compared to placebo. These results, which are consistent with two previous studies, underscore the potential that *Gilenya* holds for patients and the MS community.

Novartis is working with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) on their reviews of the benefits and risks of *Gilenya* that were initiated following the report of a patient death that occurred within 24 hours after receiving the first dose of *Gilenya* in November 2011. The FDA has stated that, at this time, it cannot conclude whether the drug resulted in the November 2011 patient death. According to the EMA, the cause of that patient death is still unexplained. In addition, the EMA described 10 other deaths as being of potential interest but noted that the role of *Gilenya* in these deaths has not been established. These other events preceded the November 2011 death, and were reported to the health authorities per regulations.

During the EMA review process and following the recent consultation with the Committee for Medicinal Products for Human Use (CHMP), Novartis is in the process of notifying physicians of new interim recommendations regarding the initiation of treatment with *Gilenya* in the European Union to be effective immediately. This includes the addition of continuous electrocardiogram (ECG) monitoring during the six-hour observation period following the first dose. First dose monitoring is already recommended in the *Gilenya* label. In patients who meet certain specified criteria, monitoring should be extended.

#### **Positive Phase II results for DEB025 in hepatitis C**

A study of first-in-class DEB025 showed that it may produce early viral clearance in previously untreated patients infected with the hepatitis C virus (HCV) genotypes 2 and 3. Instead of targeting the virus directly, DEB025 targets host proteins essential for the replication of all types of HCV. DEB025 has the potential to be an effective treatment option across HCV genotypes with favorable tolerability and a high barrier to resistance, a promising development for the more than 170 million people worldwide who are infected with HCV.

#### **ALTITUDE trial with *Tekturna/Rasilez* stopped**

In late December, following the seventh interim review of data from the ALTITUDE study with *Tekturna/Rasilez*, Novartis announced that the trial was halted on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the study. The DMC concluded that patients were unlikely to benefit from treatment on top of standard anti-hypertensive medicines, and identified higher adverse events in patients receiving *Tekturna/Rasilez* in addition to standard of care as part of the trial. Following discussions with health authorities, Novartis has written to healthcare professionals worldwide recommending that hypertensive patients with diabetes should not be treated with *Tekturna/Rasilez*, or combination products containing aliskiren, if they are also receiving an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB). As an additional precautionary measure, Novartis has ceased promotion of *Tekturna/Rasilez*-based products for use in combination with an ACE inhibitor or ARB.

#### **Alcon devices approved in Japan**

The *EX-PRESS* Glaucoma Filtration Device (P50PL and P200PL) and the *WaveLight Allegretto Wave Eye-Q* Refractive Laser gained approval in Japan in the fourth quarter. The *EX-PRESS* Glaucoma Filtration Device is the first glaucoma filtration device in Japan and complements Alcon's pharmaceutical eye drops, such as *Travatan Z* and *DuoTrav*, in physicians' treatment of glaucoma patients. The filtration device provides an easier path for the physician to drain aqueous fluid from the anterior chamber of the eye, compared to the current trabeculectomy procedure, providing a more consistent surgical procedure and more predictable patient outcomes. The *Eye-Q* excimer laser has enhanced pulse frequency of 400 Hz while providing innovative and reliable eye tracking and improved ergonomics for the physician and patient.

**Positive CHMP opinion for *Nepafenac***

The EMA's Committee for Medicinal Products for Human Use adopted a positive opinion in the fourth quarter for expanding the label claim for *Nepafenac*, an ophthalmic suspension that treats eye pain and inflammation resulting from cataract surgery, adding an indication for the reduction in the risk of postoperative macular edema associated with cataract surgery in diabetic patients. Macular edema is an important complication that can lead to permanent loss of vision in patients with diabetes who undergo cataract surgery.

### **Alcon's refractive offering expanded through US approval**

The *WaveLight* EX500 Excimer Laser gained approval in the US in the fourth quarter. The *WaveLight* EX500 system improves refractive outcomes while offering additional precision and safety in laser eye surgery procedures. This approval follows the earlier certification of the *WaveLight* FS200 Femtosecond Laser in 2010, which allows Alcon to offer physicians an integrated Refractive Suite where the two lasers communicate – saving time and improving refractive outcomes.

### **Two additional Phase III studies underline Sandoz leadership in biosimilars**

In January, Sandoz announced two Phase III clinical trials for daily filgrastim (generic Neupogen®) and once-per-cycle pegfilgrastim (generic Neulasta®) in breast cancer patients eligible for myelosuppressive chemotherapy treatment. Filgrastim, a granulocyte-colony stimulating factor (G-CSF) analog, is used to prevent or treat neutropenia, a common side effect of chemotherapy characterized by low white blood cell count. Sandoz's filgrastim biosimilar is already marketed under the brand name *Zarzio* in more than 30 countries outside the US, and this study is expected to support extension of commercialization to the US. The pegfilgrastim study represents the next major step in the Sandoz global biosimilar development program, which aims to create the number one overall G-CSF franchise worldwide.

### **Growth: Meeting healthcare needs worldwide**

#### **Recently launched products fueled growth**

Benefitting from our investment in innovation, Novartis has a strong platform for growth, with several potential blockbuster products in our Pharmaceuticals portfolio, including *Gilenya*, *Tasigna*, *Lucentis*, *Galvus*, *Afinitor*, *Xolair* and *Onbrez Breezhaler*. Products launched since 2007 continued to fuel growth, contributing USD 3.7 billion or 25% of net sales in the fourth quarter and USD 14.4 billion (25% of net sales) for the full year.

Following its launch in the US in October 2010 and in parts of the EU in March 2011, *Gilenya*, the first oral treatment for multiple sclerosis, continued its strong growth trajectory with sales of USD 203 million in the fourth quarter (USD 494 million for the full year). This once daily treatment represents a major advance in the treatment of MS, a chronic and debilitating disease, as evidenced by the more than 25,000 patients currently being treated with *Gilenya* globally.

*Tasigna* (USD 207 million, +65% cc), a next-generation therapy for chronic myeloid leukemia (CML), also achieved strong growth, as studies continue to show its superiority even to *Glivec* in treating patients with this life-threatening blood cancer. *Tasigna* now represents more than 19% of our total CML franchise and achieved sales of USD 716 million for the full year (+74% cc).

Additionally, *Lucentis* (USD 550 million, +39% cc), a medicine that significantly improves vision in patients with wet age-related macular degeneration, made a very important contribution to Pharmaceuticals growth. In the first half of 2011, *Lucentis* was also approved in the EU and

Switzerland for the treatment of visual impairment due to diabetic macular edema and macular edema secondary to retinal vein occlusion, which further contributed to growth. Sales for the full year totaled USD 2.0 billion (+26% cc).

### **Accelerated growth in emerging markets**

Our long-term growth is supported by our established presence in emerging markets. Sales in our top six emerging markets – Brazil, China, India, Russia, South Korea and Turkey – grew 15% in cc in the fourth quarter resulting in USD 1.5 billion or 10% of Group net sales. The strong performance was particularly driven by Russia and China. For the full year, sales from the top six emerging markets aggregated USD 5.8 billion (10% of Group sales).

### **Solid performance across divisions**

Strong underlying growth in the fourth quarter was driven by Pharmaceuticals, Alcon and Vaccines and Diagnostics. Despite headwinds from loss of exclusivity and pricing pressures, Pharmaceuticals continued to perform strongly, with net sales of USD 8.3 billion expanding 4% (+5% cc) over the same period last year, underpinned by 38% (in cc) growth in recently launched products.

Alcon, which represents a new growth platform for Novartis, contributed USD 2.4 billion in net sales for the quarter, growing 6% (+7% cc) over the same period last year on a pro forma basis with particularly strong performances by the Surgical and Ophthalmic Pharmaceuticals franchises.

Sandoz net sales of USD 2.3 billion were down 5% (-4% cc) in the fourth quarter, impacted by additional competition to enoxaparin. Enoxaparin, our first generic blockbuster, achieved sales of USD 1.0 billion in 2011 (USD 225 million in the fourth quarter).

Vaccines and Diagnostics grew 86% (+86% cc) with net sales of USD 671 million for the fourth quarter, underpinned by advances in the meningococcal disease franchise, particularly *Menveo*, which achieved full year net sales of USD 142 million, and the resolution of shipment delays experienced in prior quarters.

The two Consumer Health businesses, OTC and Animal Health, declined 7% (-6% cc) in the fourth quarter, with net sales of USD 1.1 billion, impacted by a temporary suspension of production at one of our US Consumer Health sites in December.

### **Productivity: Improving efficiency and optimizing performance**

To free up resources for reinvestment in growth and greater shareholder returns, Novartis is focused on improving efficiency and reducing costs across all of our operations. For the full year, net sales grew 12% (cc) while core operating income increased by 16% (cc). This performance resulted in an improvement in core operating income margin in constant currencies of 1.1 percentage points, however currency had a negative impact of 1.6 percentage points, leading to a net decline in core operating income margin of 0.5 percentage points to 27.2% of net sales. This achievement was significantly ahead of the expectations we set at the beginning of the year to aim to improve core operating income margin in constant currencies. The improved performance was generated from both a stronger operating performance as well as a higher delivery of productivity benefits, which created resources equivalent to over 4 percentage points of sales.

For the quarter, net sales grew 5% (cc) while core operating income increased by 17% (cc). This performance resulted in an improvement in core operating income margin in constant currencies of 2.7 percentage points, however currency had a negative impact of 1.0 percentage points, leading to a net increase in core operating income margin of 1.7 percentage points to 24.0% of net sales.

Within manufacturing, we have two core aims: to create Manufacturing Centers of Excellence that can support the global operations of all six Novartis businesses; and to optimize the cost structure across divisions and enhance utilization rates at strategic sites to an industry-leading 80% of capacity. We announced the exit or partial exit from ten sites in 2011, totaling fourteen site exits since the program began. This enabled us to reduce excess capacity and shift strategic production to technology competence centers.

We recorded charges related to exits, impairment charges and inventory write-offs of USD 92 million in the fourth quarter, USD 269 million in full year 2011, and USD 332 million cumulatively since the program began in the fourth quarter of 2010.

Additional efficiency gains are expected by further optimizing our Marketing & Sales spend. This is part of a broader effort within Novartis to continue to reallocate resources geographically while simplifying processes across the organization. Marketing & Sales spend decreased as a percentage of net sales from 26.3% in 2010 to 25.7% in 2011.

## Edgar Filing: NOVARTIS AG - Form 6-K

Procurement is a major source of savings. By leveraging our scale, implementing global category management and creating country Centers of Excellence in key markets, we generated annual savings of USD 1.3 billion.

With regard to General & Administration expenses, the streamlining of core processes across Novartis and the implementation of core service centers for functions such as Human Resources and Finance is expected to further provide operating leverage.

Alcon, now fully integrated as the second largest division in the Novartis Group portfolio, has realized merger-related cost synergies in line with expectations. In the quarter, Alcon delivered USD 41 million of post-integration synergies, and in the full year, realized synergies amounting to USD 75 million.



**Free cash flow**

The sustainability of our strategy lies with the generation of cash flow that provides the resources for reinvestment and returns to shareholders. Cash flow is driven by a continued focus on the cash conversion cycle and operational cash flow improvements. Free cash flow was USD 3.9 billion for the fourth quarter, declining 6% from the previous year mainly as a result of the divestment of Enablex® in the fourth quarter of 2010 (USD 392 million). For full year 2011, free cash flow was USD 12.5 billion, an increase of 1% over the previous year. Free cash flow in 2010 included substantial cash flows from sales of A(H1N1) amounting to USD 1.8 billion.

**Capital structure and net debt**

Strong cash flows and a sound capital structure have allowed Novartis to invest in the future of its business through R&D and acquisitions even in turbulent times while keeping its double-A rating as a reflection of financial strength. Retaining a good balance between attractive shareholder returns, investment in the business and a sound capital structure will remain a priority in the future.

Free cash flow of USD 12.5 billion was deployed for dividend payments of USD 5.4 billion and share repurchases of USD 5.9 billion (including USD 2.4 billion repurchased indirectly via Alcon, Inc. to reduce the dilutive impact of the subsequent merger of Alcon, Inc. into Novartis AG). In total, dividends and share repurchases utilized 90% of the Group's 2011 free cash flow.

In the fourth quarter, Novartis purchased 12.2 million of own shares totaling USD 0.6 billion on the first trading line. These shares will be kept as treasury shares, mostly to cover future employee participation programs. For the full year 2011, Novartis repurchased 59.8 million shares totaling USD 3.5 billion. Of this, USD 2.4 billion was used to repurchase 39.4 million shares on the second line to reduce the dilutive impact of the share issue related to the Alcon merger, and USD 1.1 billion was used to buy 20.4 million shares on the first line to mostly cover future employee participation programs. The company will continue to acquire shares opportunistically for this purpose, such that together with the dividend a majority of free cash flow is expected to be returned to shareholders.

As of December 31, 2011, net debt stood at USD 15.2 billion. This represents a net increase of USD 0.3 billion since December 31, 2010. The peak Novartis net debt amount of USD 22.7 billion was reached at the beginning of the second quarter of 2011. This has been repaid to the extent of USD 7.5 billion by the year end. The long-term credit rating for the company continues to be double-A (Moody's Aa2; Standard & Poor's AA-; Fitch AA).

**2012 Group outlook**

**(Barring unforeseen events)**

Group constant currency net sales are expected to be in line with 2011.

## Edgar Filing: NOVARTIS AG - Form 6-K

Products launched since 2007 are expected to continue to grow strongly and compensate for the negative impacts of generic competition, lower *Tektural/Rasilez* sales (expected to be less than half of 2011 sales), anticipated price reductions and the expected reduction of enoxaparin sales. This expectation assumes a mid-year start of shipments out of the Lincoln plant.

Group core operating income margin in constant currencies is expected to be slightly below 2011 core operating income margin.

While productivity measures and margin improvements on products launched since 2007 are important contributions to improving profitability, they are not expected to fully offset the loss of margin from generic competition, price erosion, new investments necessary to sustain growth in new products and the impact of a delayed start-up of Lincoln, should it occur.

**Annual General Meeting**

**Dividend proposal**

The Board proposes a dividend payment of CHF 2.25 per share for 2011, up 2% from CHF 2.20 per share in 2010, representing the 15th consecutive dividend increase since the creation of Novartis in December 1996. Shareholders will vote on this at the 2011 Annual General Meeting scheduled for February 23, 2012. The payout ratio as a percentage of net income increased from 54.8% to 63.2%.

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

At the Annual General Meeting scheduled for February 23, 2012, the Novartis Board of Directors also proposes the re-election of Srikant Datar Ph.D., Andreas von Planta Ph.D. and Dr. Ing. Wendelin Wiedeking for a three-year term each, and William Brody M.D. Ph.D. and Rolf M. Zinkernagel M.D. for a two-year term each (due to their reaching the age limit).

The Board further recommends the election of Dimitri Azar M.D. to the Novartis Board of Directors for a three-year term. Dr. Azar, a US citizen, is Dean of the College of Medicine and Professor of Ophthalmology, Bioengineering, and Pharmacology of the University of Illinois at Chicago, USA. He holds a medical degree from the American University of Beirut, Lebanon, an Honorary MA from Harvard University and an Executive MBA from the University of Chicago, Booth School of Business. Dr. Azar is an internationally recognized ophthalmic surgeon and prolific researcher. He has been named one of The Best Doctors in America and one of the Castle Connolly Top Doctors in America annually since 1994. He holds multiple committee positions with the American Academy of Ophthalmology, is a member of the American Ophthalmological Association, and sits on the Board of Trustees of the Chicago Ophthalmological Society and the Association of Research in Vision and Ophthalmology. He has received multiple leadership awards, including the 2009 Lans Distinguished Award from the International Society of Refractive Surgery.

INDEX

<b><u>GROUP AND DIVISIONAL OPERATING PERFORMANCE</u></b>	<b>11</b>
<u>Group</u>	11
<u>Pharmaceuticals</u>	14
<u>Alcon</u>	16
<u>Sandoz</u>	17
<u>Vaccines and Diagnostics</u>	18
<u>Consumer Health</u>	19
<b><u>GROUP BALANCE SHEET AND CASH FLOW</u></b>	<b>22</b>
<b><u>PRODUCT REVIEW</u></b>	<b>24</b>
<u>Pharmaceuticals</u>	24
<u>Alcon</u>	28
<b><u>INNOVATION REVIEW</u></b>	<b>29</b>
<b><u>DISCLAIMER</u></b>	<b>32</b>
<b>CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS</b>	<b>33</b>

**GROUP AND DIVISIONAL OPERATING PERFORMANCE****Group**

	Q4 2011	Q4 2010	% change		FY 2011	FY 2010	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>14 781</b>	<b>14 199</b>	<b>4</b>	<b>5</b>	<b>58 566</b>	<b>50 624</b>	<b>16</b>	<b>12</b>
<b>Operating income</b>	<b>1 317</b>	<b>2 467</b>	<b>-47</b>	<b>-38</b>	<b>10 998</b>	<b>11 526</b>	<b>-5</b>	<b>1</b>
As % of net sales	8.9	17.4			18.8	22.8		
<b>Net income</b>	<b>1 210</b>	<b>2 265</b>	<b>-47</b>	<b>-37</b>	<b>9 245</b>	<b>9 969</b>	<b>-7</b>	<b>-2</b>
<b>EPS (USD)</b>	<b>0.49</b>	<b>0.95</b>	<b>-48</b>	<b>-40</b>	<b>3.83</b>	<b>4.28</b>	<b>-11</b>	<b>-5</b>
<b>Free cash flow</b>	<b>3 909</b>	<b>4 180</b>	<b>-6</b>		<b>12 503</b>	<b>12 346</b>	<b>1</b>	
<b>Core</b>								
<b>Operating income</b>	<b>3 550</b>	<b>3 166</b>	<b>12</b>	<b>17</b>	<b>15 909</b>	<b>14 006</b>	<b>14</b>	<b>16</b>
As % of net sales	24.0	22.3			27.2	27.7		
<b>Net income</b>	<b>3 011</b>	<b>2 803</b>	<b>7</b>	<b>12</b>	<b>13 490</b>	<b>12 029</b>	<b>12</b>	<b>15</b>
<b>EPS (USD)</b>	<b>1.23</b>	<b>1.14</b>	<b>8</b>	<b>13</b>	<b>5.57</b>	<b>5.15</b>	<b>8</b>	<b>11</b>

**Fourth quarter****Net sales**

Net sales rose 4% (+5% cc) to USD 14.8 billion in the fourth quarter. The strengthening of the US dollar against most major currencies negatively impacts sales by 1%. Sales were up mainly due to a strong performance from recently launched products, which contributed USD 3.7 billion or 25% to total net sales for the Group and grew 30% (in USD, excluding the impact of A(H1N1) pandemic flu vaccine) over the previous-year quarter.

**Group operating income**

Operating income was down 47% (-38% cc) to USD 1.3 billion. Exceptional income and expense in the fourth quarter amounted to a net USD 1.5 billion expense compared to USD 397 million expense in the prior year. The strengthening of the US dollar, combined with the already strong Swiss franc, resulted in a negative currency impact of 9 percentage points.

The net exceptional charge of USD 1.5 billion (2010 USD 397 million) comprised charges of USD 1.7 billion (2010 USD 789 million) offset by exceptional income of USD 186 million (2010 USD 392 million mainly related to the Enablex® divestment). Exceptional charges included: USD 903 million for *Tekturna/Rasilez* (comprising USD 250 million intangible asset impairment, USD 314 million property, plant and equipment impairment, and USD 339 million other exceptional charges), USD 163 million related to the discontinuation of the PRT128 (elinogrel) and SMC021 (oral calcitonin) development programs (comprising USD 103 million intangible asset impairment, USD 47 million property, plant and equipment impairment, and USD 13 million other exceptional charges), a charge of USD 115 million (USD 10 million of intangible asset impairment charge and USD 105 million of other exceptional charges) related to the temporary suspension of production at one

## Edgar Filing: NOVARTIS AG - Form 6-K

of our US Consumer Health sites, Alcon integration charges of USD 61 million, and restructuring costs of USD 288 million (including USD 92 million relating to the streamlining of our manufacturing network, of which USD 53 million in Switzerland, and other restructuring charges of USD 196 million, of which USD 154 million in Switzerland). Exceptional income includes a USD 106 million reduction of a contingent consideration obligation in Sandoz. In the prior year, there was an exceptional income of USD 392 million. For the fourth quarter, acquisition-related items amounted to USD 61 million compared to USD 386 million in 2010, mainly related to Alcon. Amortization of intangible assets amounted to USD 742 million compared to USD 302 million in 2010 mainly as a result of the Alcon acquisition.

Core operating income, which excludes the exceptional items identified above together with amortization of intangible assets, increased by 12% (+17% cc) to USD 3.6 billion. Core operating income margin in constant currencies increased by 2.7 percentage points. However, this improvement was offset by a negative currency impact of 1.0 percentage points, resulting in a net increase in core operating income margin of 1.7 percentage points to 24.0% of net sales.

### **Income from associated companies**

Income from associated companies decreased to USD 130 million from USD 175 million in the year-ago period. The impact of higher contributions over the prior-year quarter from Roche of USD 75 million to USD 119 million was more than offset by the prior-year exceptional additional revaluation gain recorded on the initial 25% interest in Alcon, Inc. of USD 174 million.

### **Interest expense and other financial income/expense**

For the fourth quarter, interest expense decreased by 11% from USD 196 million to USD 174 million. Other financial income/expense was a net expense of USD 12 million, down from USD 26 million in the prior-year period mainly due to a less negative currency result, which overcompensated lower earnings from investments as a result of the decreased average liquidity.

### **Taxes**

The tax rate (taxes as percentage of pre-tax income) decreased in the fourth quarter to 4.0% from 6.4% in the prior-year period, principally due to the tax benefit on the exceptional charges in high-tax jurisdictions in 2011.

The core tax rate (taxes as a percentage of core pre-tax income) increased to 15.3% in 2011 from 9.9% in 2010, mainly due to favorable phasing of R&D tax credits recorded in the fourth quarter of 2010.

### **Net income and EPS**

Net income decreased 47% (-37% cc), in line with the decline in operating income. EPS declined 48% (-40% cc) at a slightly higher rate than net income as a result of the increase in issued shares following the Alcon merger, partially offset by a lower impact from non-controlling interests. The average number of shares outstanding in the fourth quarter 2011 rose by 5% to 2,413 million from 2,290 million in the year ago period as a result of the shares issued for the Alcon acquisition. A total of 2,407 million shares were outstanding at December 31, 2011.

Core net income grew 7% (+12% cc), below the rate of growth of core operating income as a result of a higher core tax charge. Core EPS was up by 8% (+13% cc).

### **Full year**

## Net sales

Net sales rose 16% (+12% cc) to USD 58.6 billion, with a 4% benefit arising from the weakness of the US dollar against most major currencies during much of the year. Recently launched products (excluding the A(H1N1) pandemic flu vaccine and including Alcon on a pro forma basis for 2010) grew 38% (USD) over the previous-year period, contributing USD 14.4 billion or 25% to Group total net sales.

## Group operating income

Operating income was down 5% (+1% cc) to USD 11.0 billion. Exceptional income and expense in 2011 amounted to a net USD 1.9 billion expense compared to USD 1.3 billion expense in the prior year. The weakness of the US dollar, combined with the strong Swiss franc, resulted in a negative currency impact of 6 percentage points.

The net exceptional charge of USD 1.9 billion (2010 USD 1.3 billion) comprised charges of USD 2.9 billion (2010 USD 2.1 billion) offset by exceptional income of USD 1.0 billion (2010 USD 732 million). Exceptional charges included: *Tekturna/Rasilez* (USD 903 million, comprising USD 250 million intangible asset impairment, USD 314 million property, plant and equipment impairment, and USD 339 million other exceptional charges), USD 348 million related to the discontinuation of the PRT128 (elinogrel), SMC021 (oral calcitonin), AGO178 (agomelatine), and PTK796 development programs (comprising USD 288 million intangible asset impairment, USD 47 million property, plant and equipment impairment, and USD 13 million other exceptional charges), a charge of USD 115 million related to the temporary suspension of production at one of our US Consumer Health sites (comprising USD 10 million in intangible asset impairment and USD 105 million other exceptional charges), other intangible asset impairment charges of USD 71 million, financial asset impairment charges of USD 192 million, integration charges of USD 250 million (USD 243 million relating to Alcon), and restructuring costs of USD 492 million (including USD 269 million relating to the streamlining of our manufacturing network, of which USD 100 million in Switzerland, and other



restructuring charges of USD 223 million, of which USD 154 million in Switzerland). Exceptional income in 2011 of USD 1.0 billion (2010 USD 732 million) included divestment gains of USD 480 million and a USD 106 million reduction in a contingent consideration obligation in Sandoz. For the full year, acquisition-related expenses amounted to USD 250 million compared to USD 600 million in 2010 mainly related to Alcon. Amortization of intangible assets amounted to USD 3.0 billion compared to USD 1.1 billion in 2010 mainly as a result of the Alcon acquisition.

As a result, core operating income, which excludes the exceptional items identified above together with amortization of intangible assets, increased 14% (+16% cc) to USD 15.9 billion. Core operating income margin in constant currencies increased by 1.1 percentage points; however, this improvement was offset by a negative currency impact of 1.6 percentage points, resulting in a net decrease of 0.5 percentage points to 27.2% of net sales.

#### **Income from associated companies**

Income from associated companies in 2011 amounted to USD 528 million compared to USD 804 million in the prior-year period. The income from Roche was USD 499 million compared to USD 380 million. The prior year included a contribution from Alcon of USD 433 million, which is no longer included since Alcon, Inc. has been fully consolidated since August 25, 2010.

#### **Interest expense and other financial income/expense**

For the full year 2011, interest expense increased by 9% from USD 692 million to USD 751 million. Other financial income/expense was a net expense of USD 2 million, down from a net income of USD 64 million in the prior year mainly due to lower earnings from investments as a result of the decreased average liquidity. The currency result remained stable.

#### **Taxes**

The tax rate (taxes as a percentage of pre-tax income) decreased to 14.2% in 2011 from 14.8% in 2010, mainly due to the favorable impact of fully consolidating Alcon, Inc. and related tax structure reorganization.

The core tax rate (taxes as a percentage of core pre-tax income) decreased to 15.3% in 2011 from 16.6% in 2010, mainly due to the favorable impact of fully consolidating Alcon, Inc. and related tax structure reorganization.

#### **Net income and EPS**

## Edgar Filing: NOVARTIS AG - Form 6-K

Net income decreased 7% (-2% cc) to USD 9.2 billion, more than the decline in operating income as a result of lower associated company income, higher financing costs following the Alcon acquisition, partly offset by a lower tax rate (14.2% compared to 14.8%). EPS declined 11% (-5% cc), more than the decline in net income, mainly as a result of the increase in issued shares following the Alcon merger, partially offset by a lower impact from non-controlling interests. The average number of shares outstanding in 2011 rose 4% to 2,382 million from 2,286 million in the year ago, while a total of 2,407 million shares were outstanding at December 31, 2011.

Core net income grew 12% (+15% cc) to USD 13.5 billion broadly in line with core operating income. Core EPS was up by 8% (+11% cc): a lower rate than net income as a result of a higher number of outstanding shares in 2011.

**Pharmaceuticals**

	Q4 2011	Q4 2010	% change		FY 2011	FY 2010	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>8 313</b>	<b>7 970</b>	<b>4</b>	<b>5</b>	<b>32 508</b>	<b>30 306</b>	<b>7</b>	<b>4</b>
<b>Operating income</b>	<b>825</b>	<b>2 201</b>	<b>-63</b>	<b>-53</b>	<b>8 296</b>	<b>8 471</b>	<b>-2</b>	<b>4</b>
As % of net sales	9.9	27.6			25.5	28.0		
<b>Core operating income</b>	<b>2 289</b>	<b>2 187</b>	<b>5</b>	<b>12</b>	<b>10 040</b>	<b>9 586</b>	<b>5</b>	<b>8</b>
As % of net sales	27.5	27.4			30.9	31.6		

**Fourth quarter****Net sales**

Net sales grew 4% (+5% cc) to USD 8.3 billion, driven by 10 percentage points of volume growth and flat pricing, partly offset by the combined effect of generic entries and product divestments of 5 percentage points. Products launched since 2007 generated USD 2.5 billion of net sales, growing 38% in constant currencies over the same period last year. These recently launched products *Lucentis*, *Exforge*, *Exelon Patch*, *Exjade*, *Reclast/Aclasta*, *Tekturna/Rasilez*, *Tasigna*, *Afinitor*, *Onbrez Breezhaler*, *Ilaris*, *Fanapt* and *Gilenya* now comprise 30% of division sales, compared to 23% in the same period last year.

Europe (USD 2.8 billion, 0% cc) maintained strong volume growth of 13 percentage points, offsetting a negative pricing impact of 7 percentage points and the effect of generic entries of 6 percentage points. Recently launched products continued to grow strongly in European countries, contributing 38% of net sales for the region. US sales (USD 2.6 billion, 2% cc) benefitted from strong growth for *Tasigna* and *Gilenya*, which offset the generic competition for *Femara* and high-dose *Lotrel*. Latin America and Canada (USD 0.8 billion, +12% cc) achieved strong growth rates, and Japan's sales (USD 1.1 billion, +7% cc) improved versus the same period last year primarily due to new launches. The top six emerging markets (USD 0.8 billion, +12% cc) were led by particularly strong growth in China, India and Russia.

Most strategic franchises contributed to business expansion. Oncology (USD 2.7 billion, +2% cc) delivered strong underlying growth, suppressed by generic competition for *Femara* (USD 134 million, -62% cc) in the US and Europe. Growth was driven by the sustained performance of *Gleevec/Glivec* and *Tasigna* (combined sales of USD 1.4 billion, +14% cc), as well as *Sandostatin* (USD 374 million, +7% cc) and the recently launched *Afinitor*, which added USD 133 million (+66% cc). Cardiovascular and Metabolism franchise performance (USD 1.9 billion, -7% cc) was underpinned by the continued strong uptake of *Galvus* (USD 199 million, +63% cc) and *Exforge* (USD 323 million, +30% cc); however, results were impacted by the sales decline in *Diovan* (USD 1.3 billion, -17% cc) due to loss of exclusivity in the EU. The Neuroscience and Ophthalmics franchise (USD 1.3 billion, +41% cc) saw strong growth from *Gilenya* (USD 203 million), following successful launches in both the US and Europe, and from *Lucentis* (USD 550 million, +39% cc).

**Operating income**

Operating income decreased 63% (-53% cc) to USD 0.8 billion. Exceptional items including amortization amounted to a net USD 1.5 billion expense compared to USD 14 million income in the previous year. Exceptional items include charges for *Tekturna/Rasilez* of USD 903 million, restructuring charges of USD 274 million mainly related to the R&D restructuring announced in the third quarter earnings release and to the

Edgar Filing: NOVARTIS AG - Form 6-K

streamlining of our manufacturing network, impairment and other charges of USD 163 million related to the discontinuation of the PRT128 (elinogrel) and SMC021 development programs. The prior-year period includes Enablex® divestment income of USD 392 million.

Core operating income increased 5% (+12% cc) to USD 2.3 billion. Core operating income margin in constant currencies improved by 1.9 percentage points, but this improvement was mostly offset by a negative currency impact of 1.8 percentage points, resulting in a net improvement in core operating income margin of 0.1 percentage points to 27.5% of net sales. Gross margin declined by 1.5 percentage points, before negative currency effects of 0.6 percentage points, due to increased royalties for *Lucentis* and *Gilenya* and unfavorable product mix. R&D expenses decreased by 1.3 percentage points of net sales in constant currencies. Marketing & Sales and General & Administration expenses improved margin by 1.3 percentage points (cc), benefiting from continuing productivity efforts despite significant investments in new product launches. Other Income & Expense, net, improved margin by 0.8 percentage points (cc) mainly due to cost phasing in the same period last year.

## **Full year**

### **Net sales**

Net sales expanded 7% (+4% cc) to USD 32.5 billion driven by 9 percentage points of volume, partly offset by a negative pricing impact of 1 percentage point and the combined impact of generic entries and product divestments of an additional 4 percentage points. Recently launched products contributed USD 9.2 billion of net sales, growing 35% in constant currencies over the previous year. These products now represent 28% of division sales compared to 22% in 2010.

Europe remained the largest region (USD 11.6 billion, +2% cc) for Pharmaceuticals, particularly benefiting from recently launched products, which generated 35% of net sales, more than offsetting health care cost-containment measures and generic erosion. The US (USD 10.0 billion, 0% cc) contributed 31% of net sales for the division. Japan's performance (USD 3.9 billion, +7% cc) improved versus prior year due to new launches. Latin America and Canada (USD 3.0 billion, +10% cc) achieved strong growth rates. The top six emerging markets (USD 3.2 billion, +7% cc) were led by double-digit growth from China and India.

### **Operating income**

Operating income decreased 2% (+4% cc) to USD 8.3 billion. Exceptional items including amortization amounted to a net USD 1.7 billion expense compared to USD 1.1 billion expense in 2010. Exceptional items include *Tektural/Rasilez* charges of USD 903 million, restructuring charges of USD 420 million and other intangible asset impairments of USD 302 million (mainly AGO178, PTK796, PRT128 and SMC021). These were partly offset by higher prior-year impairment charges, and divestment income from Elidel® (USD 324 million) and from ophthalmic pharmaceutical products related to the Alcon acquisition (USD 81 million).

Core operating income grew 5% (+8% cc) to USD 10.0 billion. In constant currencies, core operating income margin increased by 1.4 percentage points due to continuing productivity efforts. However, this improvement was offset by a negative currency impact of 2.1 percentage points, resulting in a net decrease in core operating income margin of 0.7 percentage points to 30.9% of net sales. The underlying gross margin decreased by 0.6 percentage points (cc) mainly driven by increased royalties. Functional costs which include General & Administration, Marketing & Sales and R&D expenses improved by 2.0 percentage points, driven by productivity gains in Marketing & Sales and R&D despite significant investments in new product launches. Other Income & Expense, net, remained flat in constant currencies.



**Alcon****Restated**

	Q4 2011 USD m	Q4 2010 USD m	FY 2011 USD m	FY 2010 USD m
<b>Net sales</b>	<b>2 425</b>	<b>2 285</b>	<b>9 958</b>	<b>4 446</b>
<b>Operating income</b>	<b>236</b>	<b>308</b>	<b>1 472</b>	<b>796</b>
As % of net sales	9.7	13.5	14.8	17.9
<b>Core operating income</b>	<b>796</b>	<b>718</b>	<b>3 492</b>	<b>1 350</b>
As % of net sales	32.8	31.4	35.1	30.4

**Pro forma**

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>2 425</b>	<b>2 277</b>	<b>6</b>	<b>7</b>	<b>9 949</b>	<b>9 031</b>	<b>10</b>	<b>7</b>
<b>Operating income</b>	<b>236</b>	<b>232</b>	<b>2</b>	<b>-8</b>	<b>1 461</b>	<b>1 181</b>	<b>24</b>	<b>14</b>
As % of net sales	9.7	10.2			14.7	13.1		
<b>Core operating income</b>	<b>796</b>	<b>717</b>	<b>11</b>	<b>8</b>	<b>3 490</b>	<b>3 095</b>	<b>13</b>	<b>9</b>
As % of net sales	32.8	31.5			35.1	34.3		

As the restated net sales figures prior to August 25, 2010 only include CIBA Vision and Pharmaceuticals Division Ophthalmics activities, all of the following comments are based on 2010 pro forma figures.

**Fourth quarter****Net sales**

Net sales of USD 2.4 billion rose 6% (+7% cc) on a pro forma basis. This continued strong performance was led by strong global Ophthalmic Pharmaceuticals product growth of 8% (+9% cc) and Surgical products growth of 8% (+9% cc).

US sales rose 8%, led by a strong performance of the Ophthalmic Pharmaceuticals franchise (mainly infection/inflammation, dry eye, and otic/nasal products), as well as contact lenses. Sales in non-US markets increased 5% (+6% cc) to USD 1.5 billion driven by the Ophthalmic Pharmaceuticals and Surgical product categories. Sales in the top six emerging markets increased 18% (+23% cc), led by China, South Korea and India.

## **Operating income**

Operating income of USD 236 million rose 2% (-8% cc) on a pro forma basis. Fourth quarter operating income includes amortization of intangible assets (USD 477 million) and integration costs (USD 61 million).

Core operating income of USD 796 million increased by 11% (+8% cc) on a pro forma basis. Alcon delivered strong operating leverage through productivity gains and the realization of post-integration synergies (USD 41 million). Core operating income margin in constant currencies increased by 0.2 percentage points on a pro forma basis, with a positive currency impact of 1.1 percentage points, resulting in a net increase in core operating income margin of 1.3 percentage points to 32.8% of net sales. Gross margin was 74.1% of net sales and broadly in line with the previous-year period. R&D expenses represented 9.7% of net sales, also in line with the 2010 period. Marketing & Sales expenses, which represented 26.7% of net sales, improved by 1.5 percentage points despite increased investments in emerging markets. General & Administration expenses declined from 5.8% to 5.1% of net sales in the 2011 period, as a result of good cost management and merger-related cost synergies.

## **Full year**

### **Net sales**

Net sales of USD 10.0 billion rose 10% (+7% cc) on a pro forma basis, driven by strong global Ophthalmic Pharmaceuticals product growth of 12% (+10% cc), Surgical products growth of 11% (+8% cc), and by the top six emerging markets, which grew 26% (+22% cc) over 2010.



**Operating income**

Operating income of USD 1.5 billion rose 24% (+14% cc) on a pro forma basis. Full year operating income was impacted by the inclusion of exceptional income from a litigation settlement (USD 183 million), amortization of intangible assets (USD 1.9 billion), integration costs (USD 221 million), and the impact of manufacturing optimization (USD 57 million).

Core operating income of USD 3.5 billion increased by 13% (+9% cc) on a pro forma basis. Core operating income margin in constant currencies increased by 0.7 percentage points on a pro forma basis; in addition, there was a positive currency impact of 0.1 percentage points, resulting in a net increase in core operating income margin of 0.8 percentage points to 35.1% of net sales.

**Sandoz**

	Q4 2011	Q4 2010	% change		FY 2011	FY 2010	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>2 294</b>	2 420	<b>-5</b>	<b>-4</b>	<b>9 473</b>	8 592	<b>10</b>	<b>7</b>
<b>Operating income</b>	<b>394</b>	292	<b>35</b>	<b>33</b>	<b>1 422</b>	1 321	<b>8</b>	<b>10</b>
As % of net sales	17.2	12.1			15.0	15.4		
<b>Core operating income</b>	<b>408</b>	419	<b>-3</b>	<b>-4</b>	<b>1 921</b>	1 742	<b>10</b>	<b>11</b>
As % of net sales	17.8	17.3			20.3	20.3		

**Fourth quarter****Net sales**

Sandoz net sales declined 5% (-4% cc) to USD 2.3 billion, with 5 percentage points of volume expansion more than offset by price erosion of 9 percentage points. The volume increase was driven by strong performances in Russia, France, Spain, Japan and Italy, as well as by biosimilars.

US retail generics and biosimilars (USD 727 million, -4% cc) declined due to additional competition and associated price decline for enoxaparin (generic Lovenox®) as well as the significant 180-day launches of both Sandoz's gemcitabine and lansoprazole authorized generics in the prior-year quarter. German sales of retail generics and biosimilars (USD 343 million, -4% cc) declined compared to the prior-year quarter, but improved significantly over performance in the first nine months of 2011, absorbing the price impact of statutory health insurance tenders as well as new lower reference prices. Western Europe retail generics and biosimilars grew significantly (+9% cc), driven by strong performances in France, Spain and Italy. Emerging markets growth was led by Latin America (+14% cc) and Asia (+10% cc).

Sandoz strengthened its number one global position in the biosimilars segment (USD 77 million, +46%, +48% cc), with strong momentum across all three of its products – *Omnitrope* (human growth hormone), *Binocrit* (epoetin alfa), and *Zarzio* (filgrastim) – each of which is now the leading biosimilar in its respective market segment.

**Operating income**

Operating income increased by 33% in constant currencies to USD 394 million. The operating income margin improved by 5.1 percentage points as compared to the fourth quarter of 2010, reaching 17.2% of net sales. The operating income margin increased by 4.6 percentage points more than the core operating income margin, primarily as a result of a USD 106 million reduction of a contingent consideration obligation, partly offset by provisions for legal cases in the US.

Core operating income declined 4% in constant currencies to USD 408 million. Core operating income margin increased by 0.5 percentage points to 17.8% of net sales. Currency had a positive impact of 0.5 percentage points, resulting in a flat core operating income margin in constant currencies. Gross margin increased by 2.1 percentage points (cc), driven by favorable sales mix together with productivity improvements, partly offset by price erosion and investments into product quality programs. Marketing & Sales (-1.1 percentage points in cc) increased due to higher investments into growing businesses in Western Europe and emerging markets. R&D expenses (-0.2 percentage points in cc) increased due to investments in the development of differentiated generics such as biosimilars and respiratory products, partly offset by productivity savings. General & Administration expenses (-0.4 percentage points in cc) increased due to declining sales in the quarter. Other Income & Expense, net, (-0.4 percentage points in cc) increased mainly due to higher costs of restructuring in 2011 (below the threshold for exclusion from core).

## **Full year**

### **Net sales**

Sandoz achieved strong sales growth in 2011 (USD 9.5 billion, +10%, +7% cc) versus prior year driven by significant growth in US retail generics and biosimilars (+22% cc), with sales of over USD 1 billion for enoxaparin. Strong performances in Canada (+13% cc), Western Europe (+13% cc), Latin America (+12% cc), Asia (+12% cc) and Central and Eastern Europe (+6% cc) also contributed to growth in the full year. Germany retail generics and biosimilars declined (-13% cc) in a market that is estimated to have contracted 17% in net terms due to the impact of statutory health insurance tenders and new lower reference prices. Biosimilars grew 37% in constant currencies to USD 261 million globally. Sales volume expanded 14 percentage points due to new product launches, and Falcon (transferred from Alcon) contributed 2 additional percentage points of growth, more than compensating price erosion of 9 percentage points.

### **Operating income**

Operating income grew 10% in constant currencies over the prior year to USD 1.4 billion. The operating income margin improved by 0.5 percentage points in constant currencies, offset by a negative currency impact of 0.9 percentage points, resulting in a net decrease of 0.4 percentage points to 15.0% of net sales. The constant currency margin improvement was the result of productivity improvements, the addition of the Falcon business and income from reduction of a contingent consideration obligation, partly offset by charges and provisions for legal cases in the US (USD 204 million) as well as price erosion.

Core operating income rose 11% in constant currencies to USD 1.9 billion, as declining prices were more than offset by additional sales volume, new product launches and productivity improvements in all areas. Core operating income margin in constant currencies increased by 0.8 percentage points to 21.2% of net sales. Currency had a negative impact, resulting in a 20.3% core operating income margin.

## **Vaccines and Diagnostics**

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>671</b>	<b>361</b>	<b>86</b>	<b>86</b>	<b>1 996</b>	<b>2 918</b>	<b>-32</b>	<b>-34</b>

Edgar Filing: NOVARTIS AG - Form 6-K

<b>Operating income/loss</b>	<b>42</b>	<b>-253</b>	<b>nm</b>	<b>nm</b>	<b>-249</b>	<b>612</b>	<b>nm</b>	<b>nm</b>
As % of net sales	6.3	-70.1			-12.5	21.0		
<b>Core operating income</b>	<b>101</b>	<b>-121</b>	<b>nm</b>	<b>nm</b>	<b>135</b>	<b>1 066</b>	<b>-87</b>	<b>-85</b>
As % of net sales	15.1	-33.5			6.8	36.5		

---

nm not meaningful

**Fourth quarter**

**Net sales**

Fourth quarter net sales were USD 671 million, growing 86% in constant currencies over the prior-year period. This growth was driven primarily by continued strength in our meningococcal disease franchise, the phasing of bulk pediatric production following the resolution of shipment delays experienced in prior quarters, and higher Diagnostics sales. We also realized one-time pre-pandemic flu vaccine sales in the fourth quarter, contributing to net sales growth over the prior-year period.

**Operating income/loss**

Despite continued investment in our pipeline and meningococcal disease franchise, operating income was USD 42 million for the quarter compared to a loss of USD 253 million for the same period in 2010. The improvement was driven by higher sales in the 2011 quarter as well as USD 75 million of exceptional financial impairments and restructuring charges in the prior-year quarter.

Core operating income was USD 101 million for the period compared to a loss of USD 121 million for the same period in 2010.

**Full year**

**Net sales**

Net sales were USD 2.0 billion for the full year 2011 (-34% cc) compared to USD 2.9 billion in the prior year. The primary driver of net sales variance against the prior year was USD 1.3 billion of A(H1N1) pandemic flu vaccine sales in 2010 not repeated in 2011.

Excluding the impact of A(H1N1) pandemic flu vaccines sales in 2010, net sales growth was 22% in constant currencies, driven by growth across all strategic franchises, with a particularly strong contribution from our meningococcal disease franchise.

The growth of our meningococcal disease franchise was underpinned by *Menveo*, which continues to gain market segment share both in the US and internationally, with net sales of USD 142 million in 2011.

**Operating income/loss**

Operating loss was USD 249 million for the full year 2011 compared to an income of USD 612 million in 2010, due in large part to the operating income associated with A(H1N1) pandemic flu vaccine sales from the prior year not repeated in 2011.

Excluding the impact of A(H1N1), profitability improved, despite continued investment in our pipeline and meningococcal disease franchise, driven by solid underlying sales growth. 2011 included impairments of USD 143 million related to financial and intangible assets compared to USD 98 million in 2010; 2010 also included charges related to a legal settlement of USD 45 million and restructuring charges of USD 52 million.

## Edgar Filing: NOVARTIS AG - Form 6-K

Core operating income for the year was USD 135 million compared to USD 1.1 billion for 2010. Excluding the impact of A(H1N1), core operating income also improved over 2010.

### Consumer Health

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>1 078</b>	<b>1 163</b>	<b>-7</b>	<b>-6</b>	<b>4 631</b>	<b>4 362</b>	<b>6</b>	<b>3</b>
<b>Operating income/loss</b>	<b>27</b>	<b>124</b>	<b>-78</b>	<b>-61</b>	<b>727</b>	<b>778</b>	<b>-7</b>	<b>4</b>
As % of net sales	2.5	10.7			15.7	17.8		
<b>Core operating income</b>	<b>166</b>	<b>144</b>	<b>15</b>	<b>30</b>	<b>873</b>	<b>845</b>	<b>3</b>	<b>12</b>
As % of net sales	15.4	12.4			18.9	19.4		

### Fourth quarter

#### Net sales

Consumer Health declined 7% (-6% cc) in the fourth quarter.

OTC experienced a net sales decline in the fourth quarter mainly due to a temporary suspension of operations and voluntary product recall of *Excedrin*, *Bufferin*, *NoDoz*, and *Gas-X* products at Consumer Health's US manufacturing facility in Lincoln, Nebraska. Supplies from the Lincoln plant account for approximately 25% of OTC's total sales and are distributed mainly to customers in the US, Canada and Latin America. Product divestments earlier in the year contributed to the sales decline over the prior-year quarter. OTC maintained double-digit growth in emerging growth markets led by China and Russia where the business achieved its highest-ever monthly market share. OTC also continued to strengthen its position in Germany where it drove high-single-digit growth in consumption, despite a declining market, through product innovation and strong commercial execution.

Animal Health sales grew significantly ahead of the market outside the US, with key emerging markets contributing double-digit growth. US sales grew double-digit in the Farm Animal Business, which mostly offset the negative impact of an increasingly competitive Companion Animal market in the heartworm and flea parasiticides categories. In Europe, *Milbemax* continues to be the number one de-wormer for cats and dogs, with a new chewable formulation leading growth. The recently launched *Onsior*, a non-steroidal anti-inflammatory for cats and dogs, continued to gain market segment share across key European markets and Japan.

### **Operating income**

Operating income declined by 78% (-61% cc) to USD 27 million largely due to the provisions required for the voluntary recall of certain products. Currency had a negative impact of 17 percentage points, as Consumer Health carries a relatively high share of its cost base in Switzerland. Operating income margin declined by 8.2 percentage points to 2.5% of net sales, with a negative impact of 2.0 percentage points attributable to currency.

Core operating income grew by 15% (+30% cc) to USD 166 million. Core operating income excludes the USD 115 million exceptional charge related to the product recall. Core operating income margin in constant currencies increased by 4.7 percentage points. USD 73 million of the product recall exceptional charge relates to sales returns. As no corresponding adjustment was made at the net sales level, it had a beneficial impact of 1.0 percentage points on the core operating income margin. The underlying improvement of 3.7 percentage points compares to a low base in the previous-year quarter from an exceptionally high spend level in 2010 in the OTC business.

Core gross margin slightly increased versus prior year (+0.1 percentage points) as a result of margin improvements from manufacturing efficiencies. Marketing & Sales expenses improved strongly by 2.5 percentage points (cc) driven by rigorous cost control in OTC compared to the exceptionally high spend in the prior-year quarter, partially offset by increased investment in the US business of Animal Health. Due to our continued commitment to innovation, R&D expenses increased slightly (-0.1 percentage points cc), while General & Administration expenses improved strongly by 0.8 percentage points (cc) versus previous year as a result of cost control measures and productivity improvements. Other Income and Expense, net, improved by 0.4 percentage points (cc).

### **Full year**

#### **Net sales**

OTC and Animal Health delivered combined full year sales growth of 6% (+3% cc).

OTC delivered low-single-digit growth driven by emerging markets and priority brands. In nine out of the top ten countries for OTC, volume growth outpaced the market. Cough and cold brands, including *Theraflu*, grew strongly behind sustained investment and a stronger season in several markets compared to 2010. *Voltaren* continued to grow through the use of innovative commercial models and a focus on marketing fundamentals, while *Prevacid24HR* benefitted from normalized stock movements compared to 2010. In the US, *Excedrin* sales declined in the fourth quarter due to the temporary suspension of operations and voluntary product recall at OTC's Lincoln site. Expired distribution contracts and divested brands also negatively impacted sales growth versus the prior year.



Animal Health contributed mid-single-digit sales growth over the previous year, driven by Germany, Japan, Australia and emerging markets. *CliK* and *Vetrazin* retained their leadership positions in the sheep market in Australia and the UK. *Milbemax* delivered double-digit growth as the number one cat and dog de-wormer in Europe, while *Onsior* gained market segment share across key European markets and Japan. In the swine business, *Denagard* continued to drive strong double-digit growth led by the US. Total US sales were flat despite the negative impact of a competitor entry in the heartworm and flea categories.

### Operating income

Full year operating income decreased by 7% (+4% cc) to USD 727 million, with operating income margin in constant currencies increasing by 0.2 percentage points, offset by a negative currency impact of 2.3 percentage points, resulting in an operating income margin of 15.7% of net sales.

Core operating income increased by 3% (+12% cc) to USD 873 million. Core operating income excludes the USD 115 million exceptional charge related to the product recall. Core operating income margin in constant currencies increased by 1.8 percentage points. This result demonstrates strong operating leverage with core operating income growing significantly ahead of sales. USD 73 million of the product recall exceptional charge relates to sales returns. As no corresponding adjustment was made at the net sales level, it had a beneficial impact of 0.4 percentage points on the core operating income margin. Currency negatively impacted core operating income margin by 2.3 percentage points, resulting in a net core operating income margin decrease of 0.5 percentage points to 18.9% of net sales.

Gross margin improved slightly by 0.1 percentage points (cc) driven by productivity gains that were partially offset by product mix. Marketing & Sales expenses decreased by 0.7 percentage points (cc) versus prior year driven by efficiency improvements in OTC partially offset by increased investment in the Animal Health business. R&D expenses decreased by 0.1 percentage points (cc) from productivity measures that more than offset continued investment in innovation. General & Administrative expenses decreased by 0.2 percentage points (cc) due to strong cost control. Other Income and Expense, net, improved by 0.3 percentage points (cc) largely driven by income from smaller product divestments.

## **GROUP BALANCE SHEET AND CASH FLOW**

### **Balance sheet**

#### **Assets**

The total assets at December 31, 2011 amounted to USD 117.5 billion and were USD 5.8 billion lower than the level at the beginning of the year. Total non-current assets amounted to USD 93.4 billion compared to USD 96.6 billion at the beginning of the year, and included goodwill and intangible assets, which decreased to USD 61.9 billion from USD 64.9 billion at the beginning of the year. Current assets also decreased to USD 24.1 billion from USD 26.7 billion mainly due to a reduction in marketable securities, which fell by USD 3.1 billion as a result of the transaction with Alcon minority shareholders and a decrease in inventories of USD 0.2 billion while trade receivables increased by USD 0.5 billion.

#### **Financial debt**

Total current and non-current financial debt including derivatives decreased by USD 2.8 billion to USD 20.2 billion at December 31, 2011 compared to December 31, 2010, despite the funding of acquisitions and share repurchases. The long-term financial debt of USD 13.8 billion comprises bonds and Euro Medium Term Notes totaling USD 12.7 billion and other long-term financial loans of USD 1.1 billion. The short-term financial debt of USD 6.4 billion comprises commercial paper of USD 2.2 billion and other short-term borrowings totaling USD 4.2 billion.

#### **Group equity**

The Group's equity fell by USD 3.8 billion to USD 65.9 billion at December 31, 2011 compared to December 31, 2010. Total comprehensive income amounted to USD 7.3 billion, principally due to net income for 2011 (USD 9.2 billion), offset by net actuarial losses from defined benefit plans (USD 1.4 billion) and negative currency translation movements (USD 0.6 billion). This was more than offset by dividends (USD 5.4 billion), the net effect of the purchase of treasury shares (USD 3.5 billion) coupled with the acquisition of the remaining USD 2.9 billion non-controlling interest in Alcon, Inc. and an increase from equity-based compensation (USD 0.8 billion).

The acquisition of the remaining non-controlling interests in Alcon, Inc. in 2011 was achieved in two key steps. Prior to April 8, 2011, 4.8% of Alcon, Inc. was acquired, which resulted in a reduction of Group's equity by USD 2.4 billion. On April 8, 2011, the remaining outstanding non-controlling interests were acquired by an exchange of Novartis shares with a value of USD 9.2 billion plus a contingent value payment of USD 0.5 billion. Including acquisition-related costs charged to equity of USD 0.1 billion, this resulted in total charges of USD 12.2 billion which were offset by the amount of USD 6.5 billion non-controlling interests Novartis obtained through this transaction, leading to a net reduction of USD 5.7 billion. Non-controlling interests reduced by USD 6.6 billion, mainly driven by the transaction described above.

#### **Liquidity**

The Group's debt/equity ratio improved to 0.31:1 at December 31, 2011, compared to 0.33:1 at the end of 2010 as the impact of the lower equity was more than offset by the impact of the lower financial debts. The Group's liquidity decreased from USD 8.1 billion at the end of 2010 to USD 5.1 billion at the end of 2011. Net debt at December 31, 2011 was USD 15.2 billion compared to the USD 14.9 billion at the beginning of the year.

**Cash flow**

The free cash flow for the fourth quarter of 2011 amounted to USD 3.9 billion compared to USD 4.2 billion in the year ago period mainly on account of proceeds of USD 0.4 billion from an initial cash payment from the Enablex® divestment recorded in the prior year period. Despite higher tax payments and working capital requirements, cash flow from operating activities was USD 4.7 billion, significantly higher than operating income.

Cash flow used in investing activities was USD 0.8 billion, mainly due to purchases of property, plant and equipment compared to USD 0.6 billion in the prior year period.

The cash outflow for financing activities in the fourth quarter of 2011 was USD 4.2 billion on account of repayments of financial debts of USD 3.4 billion and treasury share transactions of USD 0.7 billion.

Free cash flow for the full year was USD 12.5 billion, which represents an increase of 1% or USD 0.2 billion compared to the prior-year period. Cash flow from operating activities was USD 14.3 billion, an increase of only USD 0.2 billion as a result of the strong cash collection for A(H1N1) pandemic flu vaccines in the prior year period.

Cash outflows for investing activities were USD 0.8 billion compared to USD 15.8 billion in the prior year period. Outflows for investments in property, plant and equipment assets (USD 2.2 billion) and intangible and financial assets (USD 0.4 billion) as well as acquisition of businesses (USD 0.6 billion), mainly Genoptix, Inc. were partly compensated by inflows from the sale of marketable securities (USD 1.6 billion) and proceeds from the sales of various assets (USD 0.8 billion, mainly Elidel® marketing rights). In the prior year period, outflows for investments in property, plant and equipment assets (USD 1.7 billion) and in intangible and financial assets (USD 0.7 billion) as well as acquisition of businesses (USD 26.7 billion), mainly Alcon, were partially funded by the sale of marketable securities (USD 12.6 billion) and proceeds from the sales of various assets (USD 0.7 billion).

For the full year 2011, the cash outflow for financing activities was USD 15.0 billion. It was comprised of outflows of USD 5.4 billion for the dividend payment, of USD 3.5 billion for treasury share repurchases, USD 3.2 billion for the acquisition of the Alcon minority interests and USD 2.8 billion for the repayment of financial debts and USD 0.1 billion other financing items.

**PRODUCT REVIEW****Pharmaceuticals product review**

All comments below focus on fourth quarter movements.

**Cardiovascular and Metabolism**

	Q4 2011 USD m	Q4 2010 USD m	% change USD	cc	FY 2011 USD m	FY 2010 USD m	% change USD	cc
Hypertension medicines								
<i>Diovan</i>	1 318	1 576	-16	-17	5 665	6 053	-6	-9
<i>Exforge</i>	323	251	29	30	1 209	904	34	30
Subtotal Valsartan Group	<b>1 641</b>	<b>1 827</b>	<b>-10</b>	<b>-10</b>	<b>6 874</b>	<b>6 957</b>	<b>-1</b>	<b>-4</b>
<i>Tekturna/Rasilez</i>	108	133	-19	-18	557	438	27	24
<b>Subtotal Hypertension</b>	<b>1 749</b>	<b>1 960</b>	<b>-11</b>	<b>-11</b>	<b>7 431</b>	<b>7 395</b>	<b>0</b>	<b>-3</b>
<i>Galvus</i>	199	124	60	63	677	391	73	66
<b>Total strategic products</b>	<b>1 948</b>	<b>2 084</b>	<b>-7</b>	<b>-7</b>	<b>8 108</b>	<b>7 786</b>	<b>4</b>	<b>1</b>
Established medicines	245	309	-21	-22	1 027	1 369	-25	-29
<b>Total</b>	<b>2 193</b>	<b>2 393</b>	<b>-8</b>	<b>-8</b>	<b>9 135</b>	<b>9 155</b>	<b>0</b>	<b>-4</b>

Our Hypertension franchise consists of the Valsartan Group (which includes the *Diovan* Group and *Exforge* Group) and *Tekturna/Rasilez*.

***Diovan* Group** (USD 1.3 billion, -17% cc) worldwide sales declined due to loss of exclusivity in the EU. *Diovan* Group remains the top-selling anti-hypertensive medication worldwide, with 13.27% share of the global hypertension market.

***Exforge* Group** (USD 323 million, +30% 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 Europe, Asia and Latin America. *Exforge*, a single-pill combination of *Diovan* and the calcium channel blocker amlodipine, delivered excellent growth globally and is now available for patients in over 80 countries. *Exforge HCT*, *Exforge* with a diuretic (hydrochlorothiazide) in a single pill, is now available in over 40 countries with additional launches expected in 2012.

***Tekturna/Rasilez*** (USD 108 million, -18% cc), aliskiren, saw sales decline in the fourth quarter. In late December, following the review of data from the ALTITUDE study with *Tekturna/Rasilez*, Novartis announced that the trial was halted on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the study. As an additional precautionary measure, Novartis has ceased promotion of *Tekturna/Rasilez*-based products for use in combination with an ACE inhibitor or ARB.

**Galvus Group** (USD 199 million, +63% cc), which includes oral treatments with vildagliptin for type 2 diabetes, showed strong growth in Japan and in many European, Latin American and Asian-Pacific markets since launch in 2007. In the fourth quarter, *Galvus* received EU approval for expanded use in type 2 diabetes patients with moderate or severe renal impairment and a CHMP positive opinion for use as a monotherapy for type 2 diabetes patients who cannot take metformin. Vildagliptin is now available in nearly 90 countries with an additional launch in China expected in 2012.

## Oncology

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<b>Bcr-Abl Franchise</b>								
<i>Gleevec/Glivec</i>	1 238	1 143	8	9	4 659	4 265	9	5
<i>Tasigna</i>	207	126	64	65	716	399	79	74
<b>Subtotal Bcr-Abl Franchise</b>	<b>1 445</b>	<b>1 269</b>	<b>14</b>	<b>14</b>	<b>5 375</b>	<b>4 664</b>	<b>15</b>	<b>11</b>
<i>Zometa</i>	368	395	-7	-7	1 487	1 511	-2	-5
<i>Sandostatin</i>	374	351	7	7	1 443	1 291	12	9
<i>Femara</i>	134	351	-62	-62	911	1 376	-34	-37
<i>Exjade</i>	229	209	10	10	850	762	12	8
<i>Afinitor</i>	133	80	66	66	443	243	82	77
Other	46	37	24	26	163	181	-10	-15
<b>Total</b>	<b>2 729</b>	<b>2 692</b>	<b>1</b>	<b>2</b>	<b>10 672</b>	<b>10 028</b>	<b>6</b>	<b>3</b>

Our Bcr-Abl franchise, consisting of *Gleevec/Glivec* and *Tasigna*, continued to grow strongly, reaching USD 1.4 billion (+14% cc) in the fourth quarter.

*Gleevec/Glivec* (USD 1.2 billion, +9% cc) continued to grow as a targeted therapy for Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), and as a treatment for metastatic, unresectable and adjuvant (post-surgery) KIT+ gastrointestinal stromal tumors.

*Tasigna* (USD 207 million, +65% cc) is growing rapidly as a next-generation targeted therapy for adult patients with Ph+ CML in chronic phase. It has received regulatory approval in the first-line indication in more than 50 markets globally, including the US, EU, Japan and Switzerland, with additional submissions pending worldwide. *Tasigna* is approved as a second-line treatment for patients with Ph+ CML chronic and accelerated phases in more than 95 countries. *Tasigna* market share continues to rise in both the first-line and second-line Ph+ CML settings.

*Zometa* (USD 368 million, -7% cc) is a leading treatment to reduce or delay skeletal-related events in patients with bone metastases from solid tumors and multiple myeloma. In Europe and the US, *Zometa* is available in a ready-to-use formulation to increase convenience of administration. While sales in Europe grew, competition in the US caused a 5% decline in total in the fourth quarter.

*Sandostatin* (USD 374 million, +7% cc) continued to benefit from the increasing use of *Sandostatin LAR* in key markets to treat symptoms of patients with neuroendocrine tumors, as well as approvals in more than 25 countries for the delay of tumor progression in patients with midgut carcinoid tumors. It is currently under review in more than 20 additional countries for this indication.

*Femara* (USD 134 million, -62% cc), a treatment for early stage and advanced breast cancer in postmenopausal women, experienced an expected decline in sales due to multiple generic entries in the US, Europe and other key markets.

## Edgar Filing: NOVARTIS AG - Form 6-K

**Exjade** (USD 229 million, +10% cc), a once-daily oral therapy for transfusional iron overload, approved in more than 100 countries, continued to grow outside the US at a double-digit rate. Regulatory filings were submitted in the EU and are underway in the US for *Exjade* use in patients with non-transfusion-dependent thalassemia based on results from THALASSA, a pivotal study presented at the American Society of Hematology meeting in December.

**Afinitor** (USD 133 million, +66% cc), an oral inhibitor of the mTOR pathway used across multiple diseases, continued to achieve strong growth in key markets. The first approved treatment for patients with advanced renal cell carcinoma following VEGF-targeted therapy, *Afinitor* is currently approved in more than 80 countries for this indication. *Afinitor* is also approved in 39 countries, including the US, EU and Japan, for the treatment of advanced pancreatic neuroendocrine tumors. In addition, everolimus, the active ingredient in *Afinitor*, is approved in 40 countries (including in the US as *Afinitor* and in the EU as *Votubia*) for the treatment of subependymal giant cell astrocytomas associated with tuberous sclerosis. Everolimus is available under the trade names *Zortress/Certican* for use in other non-oncology indications and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.



## Neuroscience and Ophthalmics

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<i>Lucentis</i>	550	394	40	39	2 050	1 533	34	26
<i>Exelon/Exelon Patch</i>	271	256	6	8	1 067	1 003	6	4
<i>Comtan/Stalevo</i>	152	157	-3	-3	614	600	2	-1
<i>Gilenya</i>	203	11	nm	nm	494	15	nm	nm
<i>Extavia</i>	39	40	-3	-4	154	124	24	19
Other (including <i>Fanapt</i> )	45	41	10	12	159	190	-16	-23
<b>Total strategic products</b>	<b>1 260</b>	<b>899</b>	<b>40</b>	<b>41</b>	<b>4 538</b>	<b>3 465</b>	<b>31</b>	<b>25</b>
Established medicines	133	148	-10	-9	547	567	-4	-8
<b>Total</b>	<b>1 393</b>	<b>1 047</b>	<b>33</b>	<b>34</b>	<b>5 085</b>	<b>4 032</b>	<b>26</b>	<b>21</b>

nm not meaningful

*Lucentis* (USD 550 million, +39% cc) continued to grow strongly as the only anti-VEGF therapy licensed across three ocular indications: wet age related macular degeneration (AMD), visual impairment due to diabetic macular edema (DME), and visual impairment due to macular edema secondary to retinal vein occlusion (RVO). In wet AMD, *Lucentis* is the standard first-line therapy and the only medicine approved in more than 100 countries to significantly improve vision in patients with this disease. In December, it was approved in this indication in China. *Lucentis* is approved for the treatment of visual impairment due to DME and macular edema secondary to RVO in more than 50 countries, including Australia this quarter. Genentech/Roche holds the rights to *Lucentis* in the US.

*Exelon/Exelon Patch* (USD 271 million, +8% cc) combined sales showed continued growth. *Exelon Patch*, the transdermal form of the medicine, grew 13% and generated 78% of total *Exelon* sales in the fourth quarter. *Exelon Patch* is approved for the treatment of mild-to-moderate Alzheimer's disease dementia in more than 80 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia.

*Gilenya* (USD 203 million), a once-daily oral therapy for relapsing remitting and/or relapsing forms of multiple sclerosis (MS) in adult patients, continued to show rapid growth. *Gilenya* is now approved in more than 55 countries, with more than 25,000 patients on the commercial product. *Gilenya* is licensed from Mitsubishi Tanabe Pharma Corporation.

*Extavia* (USD 39 million, -4% cc), the Novartis-branded version of Betaferon®/Betaseron® (interferon beta-1b) for relapsing forms of MS, was impacted by tender phasing in the fourth quarter of 2011, but continued to grow in key markets delivering 19% growth for the full year. *Extavia* has been approved in over 35 countries since it received EU approval in 2008. Betaferon® and Betaseron® are registered trademarks of Bayer.

## Respiratory

	Q4 2011 USD m	Q4 2010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc

Edgar Filing: NOVARTIS AG - Form 6-K

<i>Xolair</i>	130	102	27	33	478	369	30	29
<i>TOBI</i>	79	72	10	10	296	279	6	4
<i>Onbrez Breezhaler</i>	32	17	88	94	103	33	nm	nm
<b>Total strategic products</b>	<b>241</b>	<b>191</b>	<b>26</b>	<b>30</b>	<b>877</b>	<b>681</b>	<b>29</b>	<b>27</b>
Established medicines	46	48	-4	-3	172	174	-1	-6
<b>Total</b>	<b>287</b>	<b>239</b>	<b>20</b>	<b>23</b>	<b>1 049</b>	<b>855</b>	<b>23</b>	<b>21</b>

---

nm not meaningful

**Onbrez Breezhaler** (USD 32 million, +94% cc) has continued to grow strongly across all markets as a once-daily long-acting beta2-agonist (LABA) for the maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). *Onbrez Breezhaler* is now approved in more than 80 countries, including the US, where it is approved under the name *Arcapta Neohaler*, and Japan. In Japan, Novartis announced a co-promotion agreement with Eisai Co. Ltd. starting on December 1, 2011, covering *Onbrez* Inhalation Capsules and, if approved, the investigational drugs NVA237 (glycopyrronium bromide) and QVA149 (a fixed-dose combination of indacaterol maleate and glycopyrronium bromide), to increase support for COPD patients in that country. In Germany, fourth quarter sales were negatively impacted when the reimbursed price for *Onbrez Breezhaler* was reduced below that of generic LABAs. Novartis has maintained prices for *Onbrez Breezhaler* in Germany, since it offers additional benefits over existing LABAs as described in the EU-approved label. An additional co-payment for *Onbrez Breezhaler* is now required for many patients in Germany.

**Xolair** (USD 130 million, +33% cc), a biotechnology drug approved for severe persistent allergic asthma in Europe and for moderate-to-severe persistent allergic asthma in the US, gained blockbuster status this quarter when annual global sales reached USD 1 billion (including US sales booked by Genentech/Roche). *Xolair* is now approved in 90 countries and continues to grow strongly in Europe, major Latin American markets and Japan. A Phase III trial is ongoing to support registration in China. Launches are continuing across Europe for *Xolair* Liquid, a new formulation in pre-filled syringes that enables easier administration over the original lyophilized formulation. Phase III studies are also being conducted in an additional potential indication, chronic idiopathic urticaria. Novartis co-promotes *Xolair* with Genentech/Roche in the US, and shares a portion of the operating income, but does not book any US sales. Novartis has the sole rights to market *Xolair* outside the US.

**TOBI Podhaler** (USD 79 million, including *TOBI* nebulizer solution) is approved in the EU and Canada for the treatment of chronic *Pseudomonas aeruginosa* lung infections in patients with cystic fibrosis aged six years and older. *TOBI Podhaler* (inhalation powder) is a new dry powder formulation of the antibiotic tobramycin, delivered using a more convenient, patient-friendly device that reduces administration time by 72% relative to *TOBI* (nebulizer solution) with comparable efficacy. *TOBI Podhaler* has shown rapid uptake in launch markets, reflecting the benefits it brings to patients in terms of independence and time.

### Integrated Hospital Care

	Q4 2011 USD m	Q42010 USD m	% change		FY 2011 USD m	FY 2010 USD m	% change	
			USD	cc			USD	cc
<i>Neoral/Sandimmun</i>	234	235	0	-2	903	871	4	-2
<i>Myfortic</i>	146	114	28	31	518	444	17	15
<i>Zortress/Certican</i>	49	39	26	29	187	144	30	25
<i>Ilaris</i>	12	10	20	32	48	26	85	82
Other	92	79	16	15	363	293	24	19
<b>Total strategic products</b>	<b>533</b>	<b>477</b>	<b>12</b>	<b>12</b>	<b>2 019</b>	<b>1 778</b>	<b>14</b>	<b>9</b>
Established medicines	366	400	-9	-8	1 453	1 469	-1	-4
<b>Total</b>	<b>899</b>	<b>877</b>	<b>3</b>	<b>3</b>	<b>3 472</b>	<b>3 247</b>	<b>7</b>	<b>3</b>

**Zortress/Certican** (USD 49 million, +29% cc) is a transplantation medicine indicated to prevent organ rejection in adult heart and kidney transplant patients that is available in more than 85 countries. It continues to generate solid growth, particularly in the US market, where it has been available since April 2010 for adult kidney transplantation under the trade name *Zortress*. Everolimus is marketing for other indications under the trade names *Afinitor* and *Votubia*. Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

**Ilaris** (USD 12 million, +32% cc) is approved in over 50 countries for the treatment of adults and children who suffer from cryopyrin-associated periodic syndrome, a group of rare auto-inflammatory disorders, and was recently launched in Japan.



**Alcon product review**

All comments below focus on fourth quarter movements, and are on a pro forma basis.

**Surgical**

	Q4 2011 USD m	Q4 2010* USD m	% change*		FY 2011 USD m	FY 2010* USD m	% change*	
			USD	cc			USD	cc
Cataract products	732	711	3	4	2 858	2 668	7	4
<i>Cataract IOLs</i>	318	319	0	1	1 276	1 207	6	3
Vitreoretinal products	136	113	20	21	529	424	25	21
Refractive/Other	60	36	67	65	200	129	55	51
<b>Total</b>	<b>928</b>	<b>860</b>	<b>8</b>	<b>9</b>	<b>3 587</b>	<b>3 221</b>	<b>11</b>	<b>8</b>

---

\*Pro forma

In the fourth quarter, global Surgical sales were USD 928 million, an increase of 8% (+9% cc) over the previous-year quarter. Emerging markets grew strongly, while intraocular lens unit sales in the US showed slower growth versus the 2010 period. Global sales of advanced technology intraocular lenses rose 10% (+13% cc), mostly due to strong sales of the *AcrySof IQ Toric* and *AcrySof IQ ReSTOR+3.0* intraocular lenses. The *LenSx* laser, a femtosecond laser for refractive cataract surgery, had a strong quarter of unit sales, with over 500 surgeons globally now trained to use this cutting-edge technology. The *Constellation* vitreoretinal surgical system contributed to robust sales growth within the vitreoretinal category. Strong growth in the refractive segment was driven both by sales of equipment and increased market share in the US.

**Ophthalmic Pharmaceuticals**

	Q4 2011 USD m	Q4 2010* USD m	% change*		FY 2011 USD m	FY 2010* USD m	% change*	
			USD	cc			USD	cc
Glaucoma	315	297	6	7	1 287	1 136	13	10
Allergy/Otic/Nasal	164	151	9	10	884	813	9	7
Infection/inflammation	240	219	10	11	967	839	15	14
Dry Eye/Other	197	182	8	11	810	727	11	10
<b>Total</b>	<b>916</b>	<b>849</b>	<b>8</b>	<b>9</b>	<b>3 948</b>	<b>3 515</b>	<b>12</b>	<b>10</b>

---

\*Pro forma

Global sales of Ophthalmic Pharmaceuticals products increased 8% (+9% cc) to USD 916 million. Glaucoma product sales rose 6% (+7% cc), with growth driven by non-US combination products *DuoTrav* and *Azarga*, with a combined growth of 29% (+30% cc). Infection/inflammation product sales advanced 10% (+11% cc) led by strong growth of *Nevanac* ophthalmic suspension, as well as solid performance of *Durezol* ophthalmic suspension. Dry eye products *Systane* and *Systane Balance* were the key contributors to growth in that product segment.

## Vision Care

	Q4 2011	Q4 2010*	% change*		FY 2011	FY 2010*	% change*	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
Contact lenses	408	398	3	3	1 701	1 579	8	3
Solutions/Other	173	170	2	1	713	716	0	-4
<b>Total</b>	<b>581</b>	<b>568</b>	<b>2</b>	<b>2</b>	<b>2 414</b>	<b>2 295</b>	<b>5</b>	<b>1</b>

---

\*Pro forma

Global sales of Vision Care products rose 2% (+2% cc) to USD 581 million. Contact lens growth was driven by the continued strong performance of *Air Optix*, which leads the marketplace in the multifocal segment and achieved 11% (cc) growth over the previous-year quarter, and by strong *Dailies* growth in the US. Sales of contact lenses were impacted by the discontinuation of the Specialty contact lens business as well as slower market growth in European countries. Contact lens solutions sales were led by strong double-digit growth of the *Clear Care* hydrogen peroxide solution, offset by weakness in the category for multi-purpose product sales.

**INNOVATION REVIEW**

Key developments in the fourth quarter of 2011:

**New approvals and positive opinions**

- *Lucentis* (ranibizumab) was approved by China's State Food and Drug Administration to treat wet age-related macular degeneration, making it the first licensed therapy in its class available to patients in China.
- *Rasitrio*, a single-pill combination of aliskiren, amlodipine and hydrochlorothiazide, received approval in the EU. *Rasitrio* is indicated for the treatment of hypertension in patients who can be adequately treated with aliskiren, amlodipine and hydrochlorothiazide given at the same time and dose level as in the combination pill. Novartis is working with health authorities to address the implications of the ALTITUDE (Aliskiren Trial in Type 2 Diabetes Using Cardio-Renal Endpoints) study for combination products containing aliskiren.
- *Galvus* (vildagliptin) received EU approval for expanded use in type 2 diabetes patients with moderate or severe renal impairment and a CHMP positive opinion for use as a monotherapy for type 2 diabetes patients who cannot take metformin.
- *Zortress/Certican* (everolimus) was approved in Japan as a treatment to prevent organ rejection in adult kidney transplant patients. *Certican* is already approved in Japan for heart transplantation.
- *Afinitor* (everolimus) was approved in Japan as a treatment for pancreatic neuroendocrine tumors. *Afinitor* is also approved in Japan for the treatment of non-resectable, metastatic renal cell carcinoma (advanced kidney cancer).
- In January 2012, EMA's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for *Signifor* (SOM230, pasireotide) for the treatment of Cushing's disease. If approved, *Signifor* would be the first medication in the EU targeting Cushing's disease. An EMA decision is expected in 2012.
- Also in January 2012, CHMP adopted a positive opinion for extended adjuvant *Glivec* (imatinib) therapy for patients with resected KIT+ gastrointestinal stromal tumors, based on data demonstrating a survival benefit with three years of treatment relative to one year. The FDA granted a priority review of these data for an update to the label with action expected in the first half of 2012.

## Edgar Filing: NOVARTIS AG - Form 6-K

- Alcon's *EX-PRESS* Glaucoma Filtration Device (P50PL and P200PL) and *WaveLight Allegretto Wave Eye-Q* Refractive Laser gained approval in Japan in the fourth quarter. The filtration device provides an easier path for the physician to drain aqueous fluid from the anterior chamber of the eye, compared to the current trabeculectomy procedure, providing a more consistent surgical procedure and more predictable patient outcomes. The Eye-Q excimer laser has enhanced pulse frequency of 400 Hz while providing innovative and reliable eye tracking and improved ergonomics for the physician and patient.
- The EMA's Committee for Medicinal Products for Human Use adopted a positive opinion in the fourth quarter for expanding the label claim for *Nepafenac*, adding an indication for the reduction in the risk of postoperative macular edema associated with cataract surgery in diabetic patients.
- The *WaveLight EX500* Excimer Laser, which improves refractive outcomes while offering additional precision and safety in LASIK procedures, gained approval in the US in the fourth quarter.



## Regulatory updates

- Novartis is working with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) on their reviews of the benefits and risks of *Gilenya* that were initiated following the report of a patient death that occurred within 24 hours after receiving the first dose of *Gilenya* in November 2011. The FDA has stated that, at this time, it cannot conclude whether the drug resulted in the November 2011 patient death. According to the EMA, the cause of that patient death is still unexplained. In addition, the EMA described 10 other deaths as being of potential interest but noted that the role of *Gilenya* in these deaths has not been established. These other events preceded the November 2011 death, and were reported to the health authorities per regulations. During the EMA review process and following the recent consultation with the Committee for Medicinal Products for Human Use (CHMP), Novartis is in the process of notifying physicians of new interim recommendations regarding the initiation of treatment with *Gilenya* in the European Union to be effective immediately. This includes the addition of continuous electrocardiogram (ECG) monitoring during the six-hour observation period following the first dose. First dose monitoring is already recommended in the *Gilenya* label. In patients who meet certain specified criteria, monitoring should be extended.
- NVA237 (glycopyrronium bromide) is under regulatory review in the EU, where it was submitted for approval in the third quarter of 2011 under the brand name *Seebri Breezhaler* as a once-daily maintenance treatment for chronic obstructive pulmonary disease. In the fourth quarter, NVA237 was submitted for approval in Japan, where if approved it would be co-promoted with Eisai Co. Ltd. In the US, Novartis is in dialogue with the FDA regarding additional clinical data needed to secure approval. QVA149, a fixed-dose combination of glycopyrronium bromide and indacaterol maleate, remains on track for submission in ex-US countries starting in the fourth quarter of 2012.
- QTI571 (imatinib) is expected to be submitted for approval by the end of the first quarter of 2012 in the US and EU for the treatment of pulmonary arterial hypertension (PAH). The submission will be supported by Phase III data showing that patients achieved a significant improvement in exercise capacity compared to placebo when QTI571 was added to two or more PAH-specific therapies. The submission will also include data from an extension of the Phase III IMPRES study confirming the long-term efficacy and safety profile of QTI571.
- Alcon's Phase III studies to support the new once-a-day dosing formulation of *Nepafenac* for the treatment of pain and inflammation following cataract surgery were successfully completed and a New Drug Application (NDA) was filed.
- In Alcon, the Phase III trials supporting the new uveitis indication for *Durezol* were successfully completed and the NDA was filed.
- *Dailies Total 1*, a new technology for daily disposable contact lenses in the Alcon Division, was filed under 510(k) in the US.

## Results from ongoing trials

- Updated results of the *Afinitor* Phase III study, BOLERO-2, were presented at the 2011 San Antonio Breast Cancer Symposium. The study, examining *Afinitor* (everolimus) in ER+ HER2- advanced breast cancer, showed treatment with everolimus plus hormonal therapy more than doubled progression-free survival (PFS) to 7.4 months compared to 3.2 months with hormonal therapy alone by local investigator assessment. An additional analysis based on an independent central radiology review showed everolimus extended PFS to 11.0 months compared to 4.1 months. Worldwide regulatory submissions are underway, with FDA and EMA decisions expected in 2012.

- The first placebo-controlled study of *Exjade* (deferasirox) in patients with non-transfusion-dependent thalassemia (NTDT), THALASSA, met its primary endpoint, showing that *Exjade* significantly reduced liver iron concentration. NTDT is a genetic blood disorder in which patients may accumulate excess iron in the body.

- New data from the ENESTnd clinical trial continued to show the superiority of *Tasigna* even to *Glivec* as a first-line treatment for adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). The data showed that significantly more patients achieved complete molecular response (32% taking *Tasigna* 300 mg twice daily versus 15% taking *Glivec* 400 mg once daily), and fewer patients progressed to advanced phase and blast crisis stages of disease compared to *Glivec*, leading to a significantly lower number of CML-related deaths in patients taking *Tasigna* versus *Glivec*.
- Results from ENESTcmr, the first exploratory randomized trial to investigate the impact of switching adult patients with Ph+ CML who have residual disease after at least two years of treatment with *Glivec* to *Tasigna*, showed that 23% of patients switched to *Tasigna* achieved undetectable levels of Bcr-Abl within 12 months compared to 11% who continued on *Glivec*. The study also showed a two-fold difference in confirmed undetectable complete molecular response for 13% of patients on *Tasigna* versus 6% of patients on *Glivec*, though statistical significance was not achieved (p=0.108).
- Additional results from two pivotal Phase III trials for INC424 (ruxolitinib) showed promise for the treatment of myelofibrosis, a life-threatening blood cancer. The results from COMFORT-II showed a substantial improvement in patient-reported health-related quality of life and myelofibrosis symptoms for patients receiving INC424, but remained the same or worsened for patients receiving best available therapy. Additionally, in the COMFORT-I survival analysis, INC424 demonstrated an early overall survival advantage over placebo.
- The Phase III trial GRANITE-1, which examined the efficacy and safety of everolimus versus placebo, plus best supportive care (BSC), in patients with advanced gastric cancer did not meet the primary endpoint of overall survival. Study results presented at the American Society of Clinical Oncology's 2012 Gastrointestinal Cancers Symposium showed that patients lived a median of 5.39 months when treated with everolimus plus BSC versus 4.34 months for those who received placebo plus BSC (p=0.12). The safety profile was consistent with previous studies of everolimus in the oncology setting.
- In late December, following the seventh interim review of data from the ALTITUDE study with *Tektural/Rasilez* (aliskiren), Novartis decided to terminate the trial based on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the study. The DMC concluded that patients were unlikely to benefit from treatment on top of standard anti-hypertensive medicines, and identified higher adverse events in patients receiving *Tektural/Rasilez* in addition to standard of care in the trial. Novartis has written to healthcare professionals worldwide recommending that hypertensive patients with diabetes should not be treated with *Tektural/Rasilez*, or combination products containing aliskiren, if they are also receiving an angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blocker (ARB). As an additional precautionary measure, Novartis has ceased promotion of *Tektural/Rasilez*-based products for use in combination with an ACE or ARB.
- In January, Sandoz announced two Phase III clinical trials for daily filgrastim (generic Neupogen®) and once-per-cycle pegfilgrastim (generic Neulasta®) in breast cancer patients eligible for myelosuppressive chemotherapy treatment, underlining its global leadership position in the biosimilars segment. Sandoz's filgrastim biosimilar is already marketed under the brand name *Zarzio* in more than 30 countries outside the US, and this study is expected to support extension of commercialization to the US. The pegfilgrastim study represents the next major step in the Sandoz global biosimilar development program, which aims to create the number one overall granulocyte colony-stimulating factor (G-CSF) franchise worldwide.

#### Portfolio management

## Edgar Filing: NOVARTIS AG - Form 6-K

- As part of our ongoing focus on pipeline prioritization, Novartis terminated the development of PRT128 (elinogrel), an investigational intravenous and oral anti-clotting medication.
  
- Additionally, Novartis will not pursue further clinical development with SMC021 in osteoporosis and osteoarthritis, as Phase III studies showed that while SMC021 displayed a favorable safety profile, it failed to meet key efficacy endpoints.

A full pipeline update can be found on our website at <http://www.novartis.com>.

## Disclaimer

This press release contains forward-looking statements that can be identified by terminology such as planned, expected, will, potential, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; or regarding potential future sales or earnings of the Novartis Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for any existing products in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such products will achieve any particular revenue levels. Nor can there be any guarantee that the Group, or any of its divisions, will achieve any particular financial results. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including the potential outcomes of our ongoing discussions with health authorities concerning Rasilez/Tekturna® as a result of the ALTITUDE study, and including the outcome of health authority reviews of the benefits and risks of Gilenya®; unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data, including any potential new analyses of the ALTITUDE study which may occur; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection, including the ultimate extent of the impact on the Group of the loss of patent protection on key products which commenced last year and will continue this year; unexpected product manufacturing issues, including the potential outcomes of the Warning Letter issued to us with respect to three Sandoz manufacturing facilities, and the potential outcome of the shutdown of the OTC manufacturing facility at Lincoln, Nebraska; government, industry, and general public pricing pressures; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation regarding sales and marketing practices, shareholder litigation, government investigations and intellectual property disputes; competition in general; uncertainties regarding the after-effects of the recent global financial and economic crisis; uncertainties regarding future global exchange rates and uncertainties regarding future demand for our products; uncertainties involved in the development of new healthcare products; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

## About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis has issued its annual report today, and it is available on its website at [www.novartis.com](http://www.novartis.com). Novartis will also today file its annual report on Form 20-F with the US Securities and Exchange Commission, and will post this document on [www.novartis.com](http://www.novartis.com). Novartis shareholders may receive a hard copy of either of these documents, each of which contain our complete audited financial statements, free of charge, upon request.

## Important dates

Edgar Filing: NOVARTIS AG - Form 6-K

February 23, 2012	Annual General Meeting
April 24, 2012	First quarter results 2012
July 19, 2012	Second quarter and first half results 2012

October 19, 2012      Third quarter results 2012

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: January 25th 2012

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting