

NOVARTIS AG  
Form 6-K  
October 21, 2010

# 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 October 21, 2010**

**(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>

- Investor Relations Release -

**Novartis delivers excellent performance in third quarter: recently launched products generate 20%\* of sales; *Gilenya* approved; Alcon consolidated**

**Key figures third quarter and nine months to September 30**

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>12 578</b>	11 086	13	16	<b>36 425</b>	31 341	16	15
<b>Operating income</b>	<b>2 587</b>	2 634	-2	3	<b>9 059</b>	7 345	23	23
<b>Net income</b>	<b>2 319</b>	2 112	10	14	<b>7 704</b>	6 131	26	24
<b>EPS (USD)</b>	<b>0.99</b>	0.93	6	12	<b>3.34</b>	2.69	24	22
<b>Free cash flow (before dividends)</b>	<b>2 895</b>	2 675	8		<b>8 166</b>	6 097	34	
<b>Core</b>								
<b>Operating income</b>	<b>3 699</b>	2 959	25	29	<b>10 840</b>	8 233	32	31
<b>Net income</b>	<b>3 146</b>	2 679	17	21	<b>9 226</b>	7 375	25	24
<b>EPS (USD)</b>	<b>1.36</b>	1.17	16	19	<b>4.00</b>	3.24	23	22

- **Strong financial performance in the third quarter and for nine months**
- **Net sales up 13% (+16% in constant currencies, or cc) to USD 12.6 billion;** nine months net sales up 16% (+15% cc)
- **Operating income fell 2% (+3% cc) to USD 2.6 billion** including impairment and acquisition charges of USD 794 million; nine months operating income up 23% (23% cc)
- **Core operating income up 25% (+29% cc) to USD 3.7 billion;** Core operating income margin 29.4% of net sales; nine months core operating income up 32% (+31 % cc)

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

- **Core EPS improves 16% (+19% cc) to USD 1.36**; nine months core EPS up 23% (+22% cc); third quarter EPS up 6% (+12% cc) to USD 0.99; nine months EPS +24% (+22% cc)
- **Free cash flow before dividends of USD 2.9 billion**, nine months free cash flow USD 8.2 billion
- **New product and pipeline momentum strengthens growth prospects**
- Group's recently launched products contribute 20%\* of net sales (USD 2.3 billion) with 42% growth over the previous year
- Significant innovation momentum underpinned by FDA approval of **Gilenya** as first-in-class novel therapy for relapsing multiple sclerosis; **Tasigna** received positive CHMP opinion and approval in Switzerland as first-line therapy; positive Phase III trial data for **Onbrez** over salmeterol and positive Phase III data for **MenB**
- Sandoz launches **enoxaparin** outpacing all recent injectables launches in the US; achieves **enoxaparin** sales of USD 292 million

**Basel, October 21, 2010** Commenting on the results, Joseph Jimenez, CEO of Novartis, said:

*I am pleased with our excellent performance in the third quarter. Our innovation momentum and strong execution once more drove strong sales and core operating income growth. Approvals such as Gilenya, a breakthrough first-line oral treatment for multiple sclerosis, and Tasisna, a new first-line treatment for chronic myeloid leukemia, have the potential to change patients' lives. Data on new medicines such as MenB, our meningococcal vaccine candidate, give me confidence that our pipeline will continue to deliver.*

## **GROUP REVIEW**

### **Third quarter**

Net sales rose 13% (+16% cc) to USD 12.6 billion with strong contributions from all businesses. Currency movements depressed the result by 3 percentage points. Rapid growth of recently launched products across the Group generated USD 2.3 billion in sales, representing 20%\* of total sales. Acquisitions contributed 6 percentage points to growth, mainly driven by Alcon, Inc. (Alcon) sales of USD 617 million. Volumes grew by 11 percentage points offset by a negative price effect of 1 percentage point.

Pharmaceuticals (USD 7.6 billion, +6% cc) maintained solid volume growth of 7%. Recently launched products contributed USD 1.7 billion in sales, or 22% of overall sales, representing a 30% (+34% cc) growth over the previous year. Vaccines and Diagnostics net sales were USD 0.6 billion (+21% cc) on a strong start to the flu season. Sandoz (USD 2.2 billion, +23% cc) accelerated its growth from new product launches, particularly enoxaparin, and continued strong results from the US, Canada, Russia, Italy and biosimilars. All Consumer Health businesses (USD 1.6 billion, +9% cc) had good performances and grew ahead of their markets.

Operating income decreased 2% (+3% cc) to USD 2.6 billion. Included in operating income are intangible asset impairment charges of USD 593 million in R&D expense, principally due to the termination of two development projects, and Alcon related charges of USD 217 million. Currency movements, particularly the strengthening Swiss franc, which increases costs, reduced operating income by 5 percentage points.

Core operating income, which excludes exceptional items and amortization of intangible assets, rose 25% (+29% cc) to USD 3.7 billion with Alcon contributing 7 percentage points. Performance was strong across all divisions: Pharmaceuticals grew core operating income by 9%; Vaccines and Diagnostics by 24%; Sandoz by 28%; and Consumer Health by 27%. Core operating income margin improved by 2.7 percentage points to 29.4% of net sales.

Net income increased by 10% (+14% cc) to USD 2.3 billion, primarily benefitting from a gain on the revaluation of the initial 25% stake in Alcon of USD 204 million and the impact of exceptional charges made against associated companies in 2009. Earnings per share (EPS) increased by 6% (+12% cc) to USD 0.99 from USD 0.93 in the 2009 period. EPS grew at a lower rate than net income as net income includes 100% of Alcon's results since change of majority ownership whereas EPS only recognizes the 77% share attributable to Novartis shareholders. Core net income increased by 17% (+21% cc) to USD 3.1 billion, while core EPS was up 16% (+19% cc) in the third quarter to USD 1.36 from USD 1.17 in the year-ago period.

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

The acquisition of an additional 52% of Alcon was completed on August 25 and Alcon has been consolidated thereafter. Sales of USD 617 million have been included in the third quarter; operating income (including one time acquisition effects; see page 18 for details) was USD 101 million and core operating income was USD 222 million. In addition, costs relating to the acquisition of Alcon totaling USD 96 million, have been charged to the Corporate segment resulting in a net contribution to operating income of USD 5 million. Excluding Alcon Group sales grew by 8% (10% cc), operating income declined 2% (+3% cc) and core operating income increased by 18% (22% cc). Core operating income margin was 29.1%, an improvement of 2.4 percentage points over 2009.

### **Nine months to September 30**

Net sales were up 16% (+15% cc) to USD 36.4 billion with strong improvements across all businesses. Recently launched products provided USD 7.9 billion (USD 4.3 billion in the previous year-period), contributing 22%\* of total sales. Volumes grew by 13 percentage points and price contributed a negative 1 percentage point for the nine months period. Acquisitions contributed 3 percentage points to growth, mainly driven by Alcon sales of USD 617 million.

Pharmaceuticals (USD 22.5 billion, +7% cc) maintained strong volume growth of 8 percentage points for the nine months period. Recently launched products contributed USD 4.7 billion in sales, or 21% of overall sales compared to 16% in the previous year. Vaccines and Diagnostics grew strongly to USD 2.6 billion (+151% cc) mainly through A(H1N1) pandemic flu vaccine sales of USD 1.3 billion in the first half of the year. Sandoz (USD 6.2 billion, +15% cc) realized double-digit growth versus the prior year supported by strong growth in the US, Canada, Italy, and in emerging markets. Consumer Health businesses grew 9% (8% cc) to USD 4.6 billion through delivering solid growth ahead of its respective markets.

Operating income rose 23% (+23% cc) to USD 9.1 billion on the volume-driven sales expansion and by contributions of A(H1N1) pandemic flu vaccines. Included in operating income are exceptional charges, including intangible asset impairments charged to R&D (USD 762 million) and legal settlements (USD 237 million), offset by a pension gain of USD 265 million. Operating income margin improved 1.5 percentage points to 24.9% of net sales from 23.4% in the 2009 period.

Core operating income, which excludes exceptional items and amortization of intangible assets in both periods, rose 32% to USD 10.8 billion, with Alcon contributing 3 percentage points, and the core operating income margin rose 3.5 percentage points to 29.8% of net sales from 26.3% in the previous year.

Net income advanced 26% (+24% cc) to USD 7.7 billion ahead of operating income growth. Earnings per share (EPS) rose largely in line with net income to USD 3.34 from USD 2.69 in the 2009 period. Core net income grew 25% (+24% cc) to USD 9.2 billion, while core EPS was up 23% (+22% cc) in the first nine months to USD 4.00 from USD 3.24 in the year-ago period.

Excluding Alcon sales grew for the nine months by 14% (+13% cc), operating income by 23% (+23% cc) and core operating income by 29% (+28% cc).

### **Delivering innovation, growth and productivity**

The success of Novartis is driven by a commitment to three strategic priorities: (1) **extending our lead in innovation** through the research and development of differentiated new medicines, vaccines and diagnostics; (2) **accelerating growth across all divisions** by broadening our product portfolios with new launches and increasing our presence in new markets; and (3) **improving profitability through productivity** by streamlining and simplifying our processes. Our above-market growth in the third quarter demonstrates that, despite challenges and volatility in the external environment, we are delivering on these goals.

#### **Extending our lead in innovation**

At Novartis, innovation is the core strategic focus and we continue to follow the science. We are continuing to invest in R&D for the long-term health of our pipeline: our investment in R&D is 16% of Group sales (20% of Pharmaceuticals sales), excluding impairment charges, well ahead of other companies, many of which are reducing their investment in R&D.

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

This sustained commitment to innovation is delivering differentiated pharmaceuticals, vaccines and new medicines for patients. We have made major progress with both new product approvals and additions to our marketed portfolio in the third quarter, with approvals or positive recommendations for key products like *Gilenya*, *Tasigna*, *Tekamlo*, *TOBI Podhaler*, enoxaparin and *Aflunov*, as well as significant Phase III data on *Onbrez* and *MenB*. We continue to rejuvenate our portfolio across divisions and disease areas. This demonstrates the breadth and depth of the Novartis portfolio and our non-dependence on single products or trials to support future growth.

In a significant breakthrough for patients suffering from multiple sclerosis (MS), Novartis gained US and Russian regulatory approval in the third quarter for *Gilenya* (FTY720), an effective, first-line oral treatment for relapsing multiple sclerosis, the most common form of the disease. MS is a life-long debilitating disease affecting 2.1 million patients worldwide. The approval of *Gilenya* gives patients a new and convenient treatment option that has shown significant efficacy in reducing symptoms and preventing relapses.



Our oncology franchise continues to expand its portfolio, as *Tasigna* (an improved therapy over *Glivec*) has received recommendation for approval in the EU and approval in Switzerland as a first-line treatment for patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), a form of blood cancer. *Tasigna* is already available as a first line treatment for Ph+ CML in the US. In addition, results from Phase I/II studies of the Novartis Janus kinase (JAK) inhibitor, with the investigational name INC424, indicate that it has significant benefits in treating myelofibrosis, a life-threatening type of blood cancer characterized by bone marrow failure and debilitating symptoms. Both the FDA and the EMA have granted INC424 orphan status in treating myelofibrosis.

Novartis has several other drugs in its pipeline that have promise for patients with unmet needs. SOM230 became the first medical therapy to show efficacy in treating Cushing's disease in a Phase III trial. Cushing's disease is a debilitating hormonal disorder for which there are currently no approved medicines. In another Phase III study, *Onbrez Breezhaler* was shown to be significantly better in the treatment of chronic obstructive pulmonary disease (COPD) than salmeterol, one of the current mainstays of treatment. *Onbrez Breezhaler* is already approved in more than 40 countries, including the European Union. The Phase III study evaluating AIN457 for non-infectious uveitis in patients with Behcet's disease did not meet its primary endpoint and the data do not support submission of AIN457 for this indication. We will continue to explore AIN457 in other indications.

Our Vaccines & Diagnostics Division published a Phase III study in the third quarter demonstrating that the vaccine MenB has the potential to fill a long-recognized global unmet need for a broad-coverage vaccine against the B serogroup of meningococcal meningitis (*MenB*), a deadly disease that often occurs in infants. Novartis is on track to file by the end of 2010 for *MenB* in Europe.

Sandoz achieved a significant milestone in the third quarter, winning approval of enoxaparin, the first generic version of the blockbuster anti-thrombotic Lovenox®. Enoxaparin, an injectable, was launched immediately following approval. The successful development and launch of this first-to-market generic shows the ability of Sandoz to broaden its portfolio with complex new differentiated products.

### **Accelerating growth**

New and recently launched products were a key driver of overall growth in the third quarter providing USD 2.3 billion of net sales in the 2010 period, representing 20%\* of net sales compared to 15% in the 2009 quarter. For the first nine months, recently launched products generated USD 7.9 billion of net sales, representing 22%\* of net sales compared to 14% in the previous year. Pharmaceuticals recently launched products were up 34% cc contributing 22% of total sales in the third quarter. Sandoz has also been very strong in optimizing new launches: US retail generics and biosimilars (+76% cc) delivered excellent growth due to successful first-to-market launches including enoxaparin, tacrolimus and losartan. Our ability to execute successful, large-scale launches quickly after regulatory approval is critical to meeting the diverse needs of a global patient population.

*Gilenya* (FTY720), the breakthrough oral treatment for relapsing forms of multiple sclerosis (MS), was launched in the United States in early October. *Gilenya* offers MS patients for the first time a safe and effective oral first-line treatment option and will make a significant difference in the quality of life of many MS patients. Oncology has continued to build momentum since the launch of *Afinitor* (achieving sales of USD 67 million in the third quarter) for the treatment of patients with renal cell carcinoma (RCC), with promising data in the treatment of pancreatic tumors, as well as subependymal giant cell astrocytomas (SEGA) tumors in patients with tuberous sclerosis, which was filed in the EU and the US. In the third quarter, in the cardiovascular and metabolism franchise, *Diovan* (+2% cc) continued to perform very well despite competition from generic Cozaar® in the US and Europe. *Tekturna* (+42% cc) continued to grow strongly and *Exforge* (+33% cc) also had strong growth in all global markets. *Galvus* (+114% cc) sales grew strongly in the third quarter. In Europe, *Galvus* is outpacing the overall dipeptidyl peptidase 4 (DPP-4) market.

Sandoz achieved strong overall sales growth of 18% (+23 % cc) in the third quarter versus the same period in 2009, driven by strong performance in North America, Europe, emerging markets and biosimilars. Much of this growth was driven by the success Sandoz has had in gaining market share in injectables and biosimilars. Newly launched products, such as enoxaparin, losartan, and tacrolimus, have been key in driving year-to-date growth. Of particular note is the third quarter launch of enoxaparin, the first-to-market generic version of the anti-thrombotic drug Lovenox®, which was the most successful injectables launch in the US ever. The continued strong growth in biosimilars was led by products such as *Omnitrope*, which has made steady gains against originator growth hormone deficiency treatments, as well as the launches of oncology indications of *Binocrit* (epoetin alfa) and *Zarzio* (filgrastim), setting the stage for further expansion of Sandoz's position as the biosimilars market leader.

*Menveo*, a breakthrough vaccine for meningococcal disease, has been launched in the US, EU and select other countries in Latin America and Asia-Pacific. *Menveo* is an important tool in the prevention of meningitis, a potentially deadly disease affecting almost half a million people annually. Potential indication expansions are on track and are expected to help strengthen the brand even further.

The Novartis Consumer Health medicine *Prevacid24HR*, an over-the-counter treatment for heartburn, continued to establish itself with a market share of 20% in the fast-growing proton pump inhibitors (PPI) market segment which has grown 35% year-to-date. Another Novartis Consumer Health treatment, *Voltaren*, used for joint and muscle pain, is now the number one self-medication brand in Germany, and grew by nearly 12% in the third quarter. CIBA Vision also continued to grow in its *AirOptix* contact lens brand.

Broadening our presence in emerging markets is a key element of our growth strategy. In the third quarter, we continued to serve more patients and customers in these markets, growing as a Group by 13%\* over the previous year period. Our growth rates in the top six emerging markets, which includes China, Russia, Brazil, India, South Korea and Turkey, remained also solid at 13%\*. Sandoz achieved especially strong results in emerging markets, increasing its geographic footprint with double-digit growth in the emerging market regions of Central and Eastern Europe, Asia-Pacific and the Middle East and Africa.

#### **Driving productivity**

Productivity is an essential component of performance. All parts of the business have extensive productivity programs to generate operating leverage. This provides the foundation for improved profitability while enabling investment for the future. Sustained growth cannot come without investment.

For the nine months period, core operating income margin increased 3.5 percentage points to 29.8%. Sales of A(H1N1) pandemic flu vaccines contributed approximately 2.1 percentage points of improvement, although most of this benefit will erode in the fourth quarter given the size of A(H1N1) sales in the fourth quarter of 2009.

Of the remaining core operating income margin improvement of 1.4 percentage points, Cost of Goods Sold were negative 0.8 percentage points and productivity programs generated 2.5 percentage points, of which approximately 0.9 percentage points was reinvested. The key contributions to productivity were purchasing savings with an increasing portion of purchasing now being done through global cross-divisional programs and e-sourcing, and the continued trending down of sales and marketing costs.

For the third quarter, core operating income margin grew by 2.7 percentage points with no distortion from A(H1N1) pandemic flu vaccines. Cost of Goods Sold absorbed 0.6 percentage points, other income and expenses were positive 1.4 percentage points, while productivity programs generated 3.1 percentage points, with approximately 1.7 percentage points being reinvested.

#### **Alcon, Inc.**

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

In the third quarter, Novartis completed its purchase of an additional 52% of Alcon from Nestlé resulting in 77% ownership of Alcon establishing Novartis' position as the global leader in eye care. Alcon strategically complements Novartis' portfolio, adding a world class, dynamic eye care business to its Pharmaceuticals, Vaccines and Diagnostics, Sandoz generics and Consumer Health divisions.

Opportunities for collaboration are now being explored, although any implementation will recognize the arm's-length principle. These may include utilizing the companies' complementary field forces around the potential launch of *Lucentis* for diabetic macular edema (DME). In addition, joint sourcing and procurement programs could leverage the combined purchasing volume of both companies. Other potential opportunities include optimization of lens care manufacturing and research collaborations.

### **Cash flow and net indebtedness**

The sustainability of our strategy lies with the generation of cash flow that provides the resources for reinvestment and creates shareholder return. Free cash flow before dividends generated in the third quarter totaled USD 2.9 billion, an increase of 8% over the previous year, and for the nine months amounted to USD 8.2 billion, rising 34% over the previous year.

Cash flow continues to be driven by a continued focus on the cash conversion cycle and operational cash flow improvements. Cash flow from operating activities remained flat at USD 3.2 billion in the third quarter (25.7% of net sales), and in the nine months period increased to USD 9.5 billion (26.1% of net sales).

Following completion of the acquisition of 52% of Alcon on August 25 for USD 28.3 billion, the company has gone from a net cash position to a net debt position. As of September 30, net debt stood at USD 19.0 billion. The long-term portion of the Alcon financing was put in place in 2008, 2009 and the first quarter of 2010 (with maturities spanning 3 to 10 years), with the final amount of approximately USD 8.2 billion being financed through an expanded US commercial paper program. The commercial paper financing recognizes both attractive funding rates and the strong cash generation of the business, allowing fast repayment of the commercial papers. As of September 30, USD 7.5 billion was outstanding on the US commercial paper program. The long-term credit rating for the company continues to be AA (Standard & Poor's AA-; Moody's Aa2).

## **2010 outlook**

### **(Barring unforeseen events)**

At the half-year stage we raised our sales guidance to mid- to high-single-digit in constant currency, excluding Alcon. For the full year, Group sales will include four months of Alcon and this is expected to take constant currency sales growth into the low- to mid-teens. Excluding Alcon, we maintain our previous guidance. The fourth quarter of 2009 includes A(H1N1) pandemic flu vaccine sales totaling USD 1.0 billion, which will not recur in 2010.

Group and core operating income margins are both expected to increase for the full year in 2010 as a result of business growth and the net benefit of productivity gains after reinvestments. The inclusion of Alcon is expected to be slightly negative to operating income margin and slightly positive to core operating income margin.

For the nine months, the impact of 2010 exchange rates on reported sales and operating income was broadly neutral. In the third quarter, however, the impact was negative 3 percentage points on sales and negative 5 percentage points on operating income. During the third quarter, the US dollar weakened against most currencies, although it remains relatively strong against the euro. As a result, if current exchange rates prevail for the remainder of the year, the impact on sales and operating income for the year as a whole should remain broadly neutral.

**HEALTHCARE BUSINESS REVIEW****Pharmaceuticals**

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>7 565</b>	<b>7 217</b>	<b>5</b>	<b>6</b>	<b>22 526</b>	<b>20 765</b>	<b>8</b>	<b>7</b>
<b>Operating income</b>	<b>1 844</b>	<b>2 211</b>	<b>-17</b>	<b>-12</b>	<b>6 508</b>	<b>6 486</b>	<b>0</b>	<b>0</b>
As % of net sales	24.4	30.6			28.9	31.2		
<b>Core operating income</b>	<b>2 568</b>	<b>2 364</b>	<b>9</b>	<b>12</b>	<b>7 635</b>	<b>6 853</b>	<b>11</b>	<b>10</b>
As % of net sales	33.9	32.8			33.9	33.0		

**Third quarter****Net sales**

Net sales grew 6% in constant currencies to USD 7.6 billion driven by 7 percentage points volume expansion, partly offset by government cost-containment measures in Europe and the bi-annual price cut in Japan. Recently launched products provided USD 1.7 billion of net sales in the 2010 period, growing 34% cc over the same period last year. Products launched since 2007 which include *Lucentis*, *Exforge*, *Exelon Patch*, *Exjade*, *Reclast/Aclasta*, *Tekturna/Rasilez*, *Tasigna*, *Afinitor*, *Onbrez Breezhaler*, *Ilaris* and *Fanapt* now comprise 22% of division sales compared to 18% in the 2009 quarter.

Portfolio rejuvenation benefited all regions, particularly Europe (USD 2.6 billion, +6% cc), generating 29% of its net sales from recently launched products. Volume growth in Europe was 12 percentage points with a negative price effect of 6 percentage points due to recent government cost-containment measures. The US (USD 2.6 billion, +6% cc), as well as Latin America and Canada (USD 0.8 billion, +16% cc), maintained solid growth rates. Japan's performance (USD 0.8 billion, -3% cc) was impacted by the bi-annual price cuts and the angiotensin II receptor blocker (ARB) market slowdown. The six top emerging markets (USD 710 million, +7% cc) were led by particularly strong growth in India (+26% cc) and Russia (+20% cc).

All strategic products contributed to the business expansion. Oncology (USD 2.5 billion, +9% cc), the largest franchise, was led by sustained growth of *Gleevec/Glivec* (USD 1.0 billion, +6% cc), *Femara* (USD 343 million, +6% cc), and *Sandostatin* (USD 318 million, +8% cc). Recently launched products made important contributions: *Tasigna* (USD 109 million, +97% cc), *Afinitor* (USD 67 million), *Exjade* (USD 182 million, +7% cc). Cardiovascular and Metabolism (USD 2.0 billion, +10% cc) maintained strong momentum supported by *Exforge* (USD 222 million, +33% cc), *Tekturna* (USD 113 million, +42% cc) and *Galvus* (USD 101 million, +114% cc). *Diovan* sales (USD 1.5 billion, +2% cc) also held up well, despite Cozaar® generic entry in the US and the ARB market slowdown in Japan. Neuroscience and Ophthalmics (USD 0.9 billion, +13% cc) saw rapid growth from *Lucentis* (USD 398 million, +22% cc) and *Extavia* (USD 26 million, +102% cc).

**Operating income**

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

Operating income decreased 12% in constant currencies (-17% in USD) to USD 1.8 billion. The operating income margin of 24.4% of net sales declined 6.2 percentage points, primarily impacted by intangible asset impairment charges for *Albuferon* and *Mycograb* totalling USD 584 million (*Albuferon*: USD 228 million, *Mycograb*: USD 356 million).

Core operating income grew 12% in constant currencies (+9% in USD) ahead of sales to USD 2.6 billion. The core operating income margin of 33.9% of net sales increased 1.1 percentage points compared to the same period in 2009. Cost of Goods Sold improved 0.5 percentage points driven by productivity gains partly offset by higher royalties. R&D increased 0.3 percentage points, mainly driven by phasing of clinical trial activities. Marketing & Sales expenses improved by 0.5 percentage points and is now 27.3% of net sales benefiting from continuing productivity efforts, while General & Administration expenses remained stable. Other Income and Expense improved by 0.5 percentage points mainly due to one-time expenses in the same period last year.

**Nine months to September 30****Net sales**

Net sales expanded 7% in constant currencies to USD 22.5 billion driven by 8 percentage points of volume expansion partially offset by 1 percentage point of negative price. Products launched since 2007 provided USD 4.7 billion of net sales in the 2010 period, representing 21% of net sales compared to 16% in the 2009 period (+43% cc).

Europe remained the largest region (USD 8.0 billion, +8% cc) particularly benefiting from recently launched products generating 27% of net sales. While volumes in Europe grew 12 percentage points, reported sales were affected by price erosion of 4 percentage points. The US (USD 7.5 billion, +6% cc) maintained solid growth rates, as did Latin America and Canada (USD 2.1 billion, +14% cc). Japan's performance (USD 2.4 billion) was in line with prior year despite the bi-annual price cuts and the ARB market slowdown. Top six emerging markets realized double-digit growth with the exception of Turkey, which was impacted by cost-containment measures.

**Operating income**

Operating income growth was flat compared to the prior year (USD 6.5 billion). The operating income margin of 28.9% of net sales was impacted by R&D impairment charges consisting mainly of *Albuferon*, *Mycograb* and *PTZ601* totalling USD 736 million and litigation charges of USD 178 million, partly offset by the *Famvir* settlement with Teva.

Core operating income grew 10% in constant currencies (+11% in USD) ahead of sales to USD 7.6 billion. The core operating income margin of 33.9% of net sales improved by 0.9 percentage points. Other revenues decreased 0.1 percentage points and Cost of Goods Sold increased 0.4 percentage points, mainly driven by higher royalties. R&D improved 0.3 percentage points, mainly driven by phasing of clinical trial activities. Marketing & Sales and General & Administration expenses improved by a total of 1.2 percentage points benefiting from continuing productivity efforts. Other Income and Expense remained broadly stable (-0.1 percentage points) compared to the same period last year.

**Pharmaceuticals product review****Cardiovascular and Metabolism**

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
Hypertension medicines								
<i>Diovan</i>	1 483	1 464	1	2	4 477	4 399	2	1
<i>Exforge</i>	222	171	30	33	653	475	37	37
<i>Tekturna/Rasilez</i>	113	83	36	42	305	202	51	53
<b>Subtotal</b>	<b>1 818</b>	<b>1 718</b>	<b>6</b>	<b>7</b>	<b>5 435</b>	<b>5 076</b>	<b>7</b>	<b>6</b>



Edgar Filing: NOVARTIS AG - Form 6-K

<i>Galvus</i>	101	50	102	114	267	115	132	136
<i>Lotrel</i>	80	75	7	4	224	244	-8	-9
<b>Total strategic products</b>	<b>1 999</b>	<b>1 843</b>	<b>8</b>	<b>10</b>	<b>5 926</b>	<b>5 435</b>	<b>9</b>	<b>8</b>
Established medicines	264	320	-18	-17	836	997	-16	-17
<b>Total</b>	<b>2 263</b>	<b>2 163</b>	<b>5</b>	<b>6</b>	<b>6 762</b>	<b>6 432</b>	<b>5</b>	<b>4</b>

All comments below focus on third quarter movements.

Our broad cardiovascular and metabolic portfolio continues to grow steadily with overall sales growth of 6% versus previous year. Within hypertension, Novartis continues to drive sales as the valsartan group of products shows consistent worldwide growth, reaching a market share of 15.7% of the hypertension market segment based on the three months from June to August 2010. The *Tekturna/Rasilez* group continues to grow steadily, supported by strong growth, particularly in the European Union.

**Diovan Group** (USD 1.5 billion, +2% cc) maintained strong performance despite the introduction of generic losartan and the slowdown in growth in Japan's ARB market. Worldwide sales were up 2% in the third quarter versus last year. In the US, *Diovan* Group reached sales of USD 627 million (+4% cc) in the quarter, maintaining the *Diovan* Group's leadership of the ARB segment with a 40.8% share in August year-to-date 2010 (+1.9 percentage points compared to August year-to-date 2009; source: IMS Health).

**Exforge Group** (USD 222 million, +33% cc) showed strong worldwide growth fueled by continued prescription demand in the EU, US and other key regions, and ongoing *Exforge HCT* launches in the main European and Latin American markets. *Exforge*, a single-pill combination of *Diovan* (valsartan) and the calcium channel blocker amlodipine, has delivered sustained worldwide growth since its launch in 2007. *Exforge HCT*, the first modern triple hypertension medication, which adds a diuretic in a single pill, was introduced in the US in 2009 and has gained approvals in over 20 countries worldwide.

**Tekturna/Rasilez** (USD 113 million, +42% cc) maintained its strong growth driven by its excellent performance in the EU, especially France and Germany. In August, the US Food and Drug Administration (FDA) approved *Tekamlo*, a single-pill combination of aliskiren and amlodipine, with EU review of this treatment ongoing. In September, the decision was made to withdraw a separate application for EU Marketing Authorization for *Rasival*, the combination of aliskiren and valsartan. The application was withdrawn following the Committee for Medicinal Products for Human Use (CHMP) request to provide additional data satisfying the relevant EU guidelines. Novartis was unable to provide the requested data within the timeframe of the review process. The potential for the resubmission of *Rasival* will be re-evaluated in the near future.

**Galvus/Eucreas** (USD 101 million, +114% cc), oral treatments for type 2 diabetes, continued to deliver strong growth, driven mainly by combination treatment *Eucreas/Galvusmet* which delivered 72% of total sales and grew at +123% (cc) during the third quarter versus the prior year. Growth across the *Galvus* group of products is coming from launches in France, Japan, Korea and Turkey, as well as ongoing strong performance in Europe, notably in Germany, Spain, Greece and Portugal.

## Oncology

	Q3	Q3	% change		9M 2010	9M 2009	% change	
	2010	2009	USD	cc	USD m	USD m	USD	cc
<i>Gleevec/Glivec</i>	1 015	974	4	6	3 122	2 858	9	8
<i>Zometa</i>	363	376	-3	-3	1 116	1 077	4	3
<i>Femara</i>	343	329	4	6	1 025	925	11	11
<i>Sandostatin</i>	318	300	6	8	940	839	12	11
<i>Exjade</i>	182	174	5	7	553	469	18	17
<i>Tasigna</i>	109	56	95	97	273	144	90	89
<i>Afinitor</i>	67	26	nm	nm	163	38	nm	nm
Other	54	61	-11	-9	144	180	-20	-21
<b>Total</b>	<b>2 451</b>	<b>2 296</b>	<b>7</b>	<b>9</b>	<b>7 336</b>	<b>6 530</b>	<b>12</b>	<b>11</b>

nm not meaningful

**Gleevec/Glivec** (USD 1.0 billion, +6% cc) has sustained growth through continued expansion in Ph+ chronic myeloid leukemia (CML) as well as adjuvant (post-surgery) treatment of gastrointestinal stromal tumors (GIST). *Gleevec/Glivec*, a targeted therapy for certain forms of CML and GIST, was approved in 2009 for use in adjuvant treatment of patients following complete gross resection of GIST and has since received approvals for this indication in more than 55 countries.

**Tasigna** (USD 109 million, +97% cc) has been growing rapidly through geographic and market expansion with approvals in over 85 countries as a second-line therapy for patients with certain forms of Ph+ CML resistant or intolerant to prior therapy including *Gleevec/Glivec*. *Tasigna* is now approved in the US and Switzerland, for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. In September, the CHMP issued a positive opinion recommending EU approval of *Tasigna* in this indication. Regulatory submissions in the first-line indication have also been submitted in Japan and other countries around the world. Trials are also underway examining the use of *Tasigna* in CML patients with suboptimal response to *Glivec* and in patients with metastatic and/or unresectable Kit+ GIST. In October, Novartis signed a collaboration agreement with Cepheid for the commercialization and further development of a test for monitoring of bcr-abl gene transcript. This diagnostic is expected to help physicians optimize treatment of patients with CML, indicating the depth of patients' response to tyrosine kinase inhibitor (TKI) treatments.

**Zometa** (USD 363 million, -3% cc) volume expansion offset by negative EU and Japanese pricing, continued to come from improved compliance and increased use of this intravenous bisphosphonate therapy in patients with certain types of cancer which have spread to the bone. The US FDA has extended its review of the supplemental New Drug Application for *Zometa* in the adjuvant (post-surgery) treatment of premenopausal women with early breast cancer in conjunction with hormonal therapy from the fourth quarter of 2010 to the first quarter of 2011. The extension is the result of a major amendment to the application to include an additional 12 months of data to provide a median of five years of follow up of the pivotal Austrian Breast & Colorectal Cancer Study Group Trial 12 (ABCSCG-12). This information has also been submitted to European regulatory authorities. Zoledronic acid, the active ingredient in *Zometa* (4mg), is also available under the trade names *Reclast/Aclasta* (5mg) for use in non-oncology indications with different dosing.

**Femara** (USD 343 million, +6% cc), a treatment for early stage or advanced breast cancer in postmenopausal women, achieved strong ongoing growth in key markets, including Germany, France, UK and Japan.

**Sandostatin** (USD 318 million, +8% cc), a treatment for acromegaly, benefited from the increasing use of *Sandostatin LAR* in treating symptoms of patients with neuroendocrine tumors (NET).

**Exjade** (USD 182 million, +7% cc) has continued to expand with strong growth based on new patients, expanded access and increased dosing in the US and key markets around the world. *Exjade* is currently approved in more than 100 countries as the only once-daily oral therapy for transfusional iron overload.

**Afinitor** (USD 67 million) continued regulatory submissions with a filing in the EU with the trade name *Votubia* for patients with subependymal giant cell astrocytomas (SEGA) associated with tuberous sclerosis. *Afinitor* has priority review status in the US for this indication, and *Afinitor/Votubia* has received orphan drug status in the US and EU. *Afinitor*, an oral inhibitor of the mTOR pathway, is an approved treatment for advanced renal cell carcinoma (kidney cancer) following VEGF-targeted therapy. Regulatory submissions are also on track this year in advanced neuroendocrine tumors. *Afinitor* is being studied in other tumor types with Phase III trials underway in tuberous sclerosis, breast cancer, gastric cancer, hepatocellular carcinoma and lymphoma. Everolimus, the active ingredient in *Afinitor*, is also available under the trade names *Zortress/Certican* for use in non-oncology indications.

## Neuroscience and Ophthalmics

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<i>Lucentis</i>	398	335	19	22	1 139	858	33	30
<i>Exelon/Exelon Patch</i>	244	251	-3	0	747	687	9	8
<i>Comtan/Stalevo</i>	152	141	8	9	443	402	10	9
<i>Extavia</i>	26	14	86	102	84	26	nm	nm
Other	111	108	3	6	343	343	0	-1
<b>Total strategic products</b>	<b>931</b>	<b>849</b>	<b>10</b>	<b>13</b>	<b>2 756</b>	<b>2 316</b>	<b>19</b>	<b>17</b>
Established medicines	137	145	-6	-6	419	426	-2	-5
<b>Total</b>	<b>1 068</b>	<b>994</b>	<b>7</b>	<b>10</b>	<b>3 175</b>	<b>2 742</b>	<b>16</b>	<b>14</b>

nm not meaningful

**Lucentis** (USD 398 million, +22% cc) maintained strong growth reflecting its position as the only approved medicine to significantly improve vision in patients with wet age-related macular degeneration (AMD). Novartis has filed an application in the EU for *Lucentis* for the treatment of visual impairment due to diabetic macular edema (DME) and is preparing for filing in the EU for the treatment of macular edema following retinal vein occlusion (RVO). *Lucentis* is approved in more than 85 countries for the treatment of wet AMD.

**Exelon/Exelon Patch** (USD 244 million, 0% cc) growth was flat versus the previous year. Due to increasing demand for *Exelon Patch*, the transdermal form of the medicine generates now more than 70% of total *Exelon* sales in the third quarter compared to 56% in the same period in 2009. *Exelon Patch* is approved for the treatment of mild-to-moderate Alzheimer's disease dementia in more than 75 countries, including more than 20 countries where it is also approved for dementia associated with Parkinson's disease.

**Extavia** (USD 26 million, +102% cc) continued to grow within key markets, notably Germany, Russia, Italy, Spain and the US. *Extavia*, the Novartis-branded version of Betaferon®/Betaseron® for relapsing forms of multiple sclerosis, was launched in the EU and US in 2009, and has been approved in over 30 countries.

**Gilenya** was approved as a first-line treatment for relapsing forms of multiple sclerosis in the US and for relapsing remitting multiple sclerosis in Russia. Novartis has launched *Gilenya* in the US with plans to launch in Russia in early 2011. Additionally, *Gilenya* is currently under regulatory review in the EU, where it was filed in December 2009, and with health authorities worldwide, including Canada, Switzerland, Turkey, Brazil and Australia.

### Respiratory

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<i>Xolair</i>	97	78	24	32	267	218	22	24
<i>TOBI</i>	70	76	-8	-5	207	219	-5	-5
<i>Onbrez</i>	8	0	nm	nm	16	0	nm	nm
Other	0	-2	nm	nm	0	-1	nm	nm
<b>Total strategic products</b>	<b>175</b>	<b>152</b>	<b>15</b>	<b>20</b>	<b>490</b>	<b>436</b>	<b>12</b>	<b>13</b>
Established medicines	37	40	-8	-4	126	136	-7	-9
<b>Total</b>	<b>212</b>	<b>192</b>	<b>10</b>	<b>15</b>	<b>616</b>	<b>572</b>	<b>8</b>	<b>8</b>

nm not meaningful

**Xolair** (USD 97 million, +32% cc), a biotechnology drug for severe persistent allergic asthma in Europe and moderate-to-severe persistent allergic asthma in the US, continues to show strong growth in major European markets and Latin America. *Xolair* is approved in more than 85 countries, with Phase III trials initiated in September 2010 to support a regulatory submission in China. *Xolair* Liquid, a new formulation in pre-filled syringes that will ease administration, is planned to be launched in January 2011 in the EU. Preparations are on track to start Phase III studies for a new indication, chronic idiopathic urticaria, in early 2011.

**Onbrez Breezhaler** (QAB149, indacaterol) (USD 8 million) has demonstrated promising performance following EU approval in December 2009 as a once-daily long-acting beta-2 agonist (LABA) for adults with chronic obstructive pulmonary disease (COPD). *Onbrez Breezhaler* is now available in eight European markets, with further EU launches planned during 2010, and is approved in more than 40 countries worldwide. Following a Complete Response Letter received in the US in October 2009, Novartis has completed additional studies to further characterize the dosing regimen for indacaterol. Incremental benefits have been observed with indacaterol in escalating doses from 75 mcg up to 300 mcg, with higher doses showing increasing benefit for patients, particularly those with more severe disease. Following an FDA request to explore the lower part of the dose response curve, data supporting the 75 and 150 mcg doses were submitted in the US at the end of September. Regulatory submissions have also been completed in Japan and China.



## Integrated Hospital Care

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9m 2009 USD m	% change	
			USD	cc			USD	cc
<i>Neoral/Sandimmun</i>	207	227	-9	-8	636	675	-6	-8
<i>Reclast/Aclasta</i>	143	125	14	15	408	325	26	25
<i>Myfortic</i>	122	93	31	30	330	256	29	25
<i>Zortress/Certican</i>	35	32	9	19	105	82	28	29
<i>Ilaris</i>	6	1	nm	nm	16	1	nm	nm
Other	74	62	19	19	214	165	30	27
<b>Total strategic products</b>	<b>587</b>	<b>540</b>	<b>9</b>	<b>10</b>	<b>1 709</b>	<b>1 504</b>	<b>14</b>	<b>12</b>
Established medicines	237	249	-5	-6	661	706	-6	-9
<b>Total</b>	<b>824</b>	<b>789</b>	<b>4</b>	<b>5</b>	<b>2 370</b>	<b>2 210</b>	<b>7</b>	<b>5</b>

nm not meaningful

**Reclast/Aclasta** (USD 143 million, +15% cc) is the only once-yearly osteoporosis therapy available in over 90 countries. Reinforcing its efficacy and safety profile, new long-term data from a pivotal fracture trial show *Aclasta* preserved bone mass in patients who received annual infusions for six years and the risk of new morphometric spine fractures was reduced by 52% when measured as a secondary endpoint compared to those who stopped treatment at three years. *Aclasta* is approved for up to six indications worldwide, treating a broad spectrum of patients from those with early bone loss to patients with more severe forms of this metabolic bone disease. Zoledronic acid, the active ingredient in *Reclast/Aclasta*, is also available under the trade name *Zometa* for use in oncology indications.

**Zortress/Certican** (USD 35 million, +19% cc), a transplantation medicine to prevent organ rejection in adult kidney and heart transplantation, continues to grow based on its availability in more than 80 countries and its US launch for adult kidney transplantation in April, 2010, under the brand name *Zortress* and is currently in two Phase III studies with global participation in heart transplantation, and also a worldwide study for liver transplantation. Everolimus, the active ingredient in *Zortress/Certican*, is also available under the trade name *Afinitor* for use in an oncology indication.

**Ilaris** (ACZ885, canakinumab) (USD 6 million) is a biologic medicine approved in more than 40 countries to treat adults and children aged four years and older suffering from cryopyrin-associated periodic syndrome (CAPS), a group of rare auto-inflammatory disorders that affect approximately one in one million people. ACZ885 is also in phase III development for the treatment of acute flares associated with gouty arthritis. Trials in other diseases, including type 2 diabetes and systemic juvenile idiopathic arthritis (SJIA), are also ongoing.



**Vaccines & Diagnostics**

	Q3 2010	Q3 2009	% change		9M 2010	9M 2009	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>632</b>	<b>543</b>	<b>16</b>	<b>21</b>	<b>2 557</b>	<b>1 037</b>	<b>147</b>	<b>151</b>
<b>Operating income</b>	<b>68</b>	<b>23</b>	<b>196</b>	<b>276</b>	<b>865</b>	<b>-211</b>	<b>nm</b>	<b>nm</b>
As % of net sales	10.8	4.2			33.8	-20.3		
<b>Core operating income</b>	<b>126</b>	<b>102</b>	<b>24</b>	<b>42</b>	<b>1 187</b>	<b>66</b>	<b>nm</b>	<b>nm</b>
As % of net sales	19.9	18.8			46.4	6.4		

nm Not meaningful

**Third quarter****Net sales**

Net sales were USD 632 million for the third quarter (+21% cc) compared with USD 543 million in the prior period. The flu season started strongly with revenue of approximately USD 327 million recognized in the period. Novartis Vaccines was able to ship approximately 35 million doses of seasonal influenza vaccine to US customers, an increase of over 40% from the prior period, allowing health care professionals to initiate protection of their patients well in advance of this year's flu season.

Further expansion of the vaccines business in the emerging markets and the first sales of *Menveo* outside of the US drove the continued growth of the portfolio.

**Operating income**

Operating income was USD 68 million for the third quarter 2010 compared to USD 23 million for the prior year period driven by strong seasonal flu sales.

Core operating income for the period was USD 126 million compared to USD 102 million in the prior year. Higher flu sales were impacted by poor yields resulting in higher than expected production costs. Marketing and sales spend increased in the quarter to support the global launch of *Menveo*. In addition, there was higher research and development investment to accelerate *MenB* and early pipeline candidates.

**Nine months to September 30**

**Net sales**

Net sales were USD 2.6 billion for the first nine months 2010 (+151% cc) compared to USD 1.0 billion for the year-ago period. Deliveries for supply contracts with governments around the world for A (H1N1) pandemic flu vaccines and adjuvants generated net sales of USD 1.3 billion, significantly driving the increase over the year-ago period. Excluding A (H1N1) pandemic, the business experienced strong growth (+20% cc) driven by the strong start to the flu season, expansion of the vaccines business in the emerging markets and first sales of *Menveo*.

**Operating income**

Operating income in the period was USD 865 million compared to an operating loss of USD 211 million in the year-ago period, driven substantially by contributions of A (H1N1) pandemic vaccines, whereas in the prior year period there were significant expenses related to the start-up of pandemic production.

Core operating income was USD 1.2 billion up from USD 66 million for the same period in 2009.

**Sandoz**

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>2 177</b>	<b>1 850</b>	<b>18</b>	<b>23</b>	<b>6 151</b>	<b>5 350</b>	<b>15</b>	<b>15</b>
<b>Operating income</b>	<b>415</b>	<b>312</b>	<b>33</b>	<b>34</b>	<b>1 014</b>	<b>850</b>	<b>19</b>	<b>18</b>
As % of net sales	19.1	16.9			16.5	15.9		
<b>Core operating income</b>	<b>492</b>	<b>385</b>	<b>28</b>	<b>29</b>	<b>1 306</b>	<b>1 039</b>	<b>26</b>	<b>24</b>
As % of net sales	22.6	20.8			21.2	19.4		

**Third quarter****Net sales**

Sandoz accelerated its growth (USD 2.2 billion, +18%, +23% cc) versus prior year as 30 percentage points of volume expansion came from new product launches, particularly enoxaparin (generic Lovenox®), which achieved sales of USD 292 million. The inclusion of EBEWE Pharma's specialty generics business contributed 4 percentage points in the quarter. Continued strong results from the US, Canada, Russia, Poland, Italy, the Middle East and North Africa; and biosimilars performance, which more than offset the price erosion of 7 percentage points.

US retail generics and biosimilars (+76% cc) continued to deliver excellent growth due to successful execution of first-to-market launches including enoxaparin, tacrolimus, losartan and lansoprazole. German retail generics and biosimilars (-15% cc) declined compared to the prior year due to negative market growth driven by the impact of statutory health insurance tenders and new lower reference prices. Western Europe retail generics and biosimilars (+13%) grew positively despite government price cuts. Emerging markets growth accelerated particularly in the Middle East, Turkey and Africa (+41% cc) and Asia-Pacific (+19% cc), with Central and Eastern Europe continuing to grow strongly at +19% cc. Sandoz sustained its top position in biosimilars (+41% cc) with good momentum based on key launches in the oncology indications of *Binocrit* (epoetin alfa) and *Zarzio* (filgrastim) as well as continued growth in *Omnitrope* (human growth hormone).

**Operating income**

Operating income grew 33% (+34 cc) to USD 415 million, as the operating income margin improved 2.2 percentage points to 19.1% of net sales. Operating income margin increased 0.4 percentage points faster than core operating income margin improvement of 1.8 percentage points mainly due to a lower level of intangible asset impairments in 2010 than in the prior year quarter.

Core operating income rose 28% to USD 492 million, resulting in the core operating income margin increase of 1.8 percentage points to 22.6% of net sales. Gross profit margin decreased 3.1 percentage points mainly due to a significantly different sales mix than in the prior year quarter plus higher inventory write-offs. Marketing & Sales (15.8% of net sales; +1.2 percentage points) improved core operating income margin as they rose slower than sales due to higher productivity, while fully funding investments in growing businesses. R&D costs declined (6.0% of net sales; +2.2 percentage points) and also improved core operating income margin due to the recovery of co-development expenses from an external partner as well as continued productivity savings. The savings were achieved even as Sandoz has continued to invest in the development of differentiated generics, such as biosimilars, oncological injectables and respiratory products. General & Administration costs (3.7% of net sales;

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

+1.4 percentage points) decreased due to ongoing cost-containment measures. Other Income & Expense decreased (1.8% of net sales; +0.1 percentage points) mainly due to sundry asset disposals.

### Nine months to September 30

#### **Net sales**

Sandoz achieved double-digit sales growth in the first nine months (USD 6.2 billion, +15%, +15% cc) versus prior year supported by strong growth in US retail generics and biosimilars (+46% cc) and emerging markets such as Central and Eastern Europe (+15% cc), Asia-Pacific (+21% cc) and the Middle East, Turkey and Africa (+19% cc). Sales volumes expanded 22 percentage points due to new product launches, the inclusion of EBEWE Pharma's specialty generics business (contributing 5 percentage points) and continued strong results from biosimilars which together more than compensated for price erosion of 7 percentage points.

## Operating income

Operating income in the first nine months grew 19% versus prior year to USD 1.0 billion. The operating income margin increased 0.6 percentage points to 16.5% of net sales. The operating income margin increase in the first nine months as compared to the growth in core operating income margin of 1.8 percentage points reflected the acquisition-related charges for the integration of EBEWE Pharma, one-time charges for the termination of a co-development agreement and provisions for legal settlements.

Core operating income rose 24% cc to USD 1.3 billion, as the core operating income margin improved by 1.8 percentage points to 21.2% of net sales. There were lower sales to other divisions (-0.4 percentage points), higher Other revenues (+0.1 percentage points) and higher Cost of Goods Sold (-1.1 percentage points). These impacts however were more than offset by a number of positive factors, including: Marketing & Sales costs, which were lower by 0.4 percentage points due to productivity improvements partly offset by investments in growth areas; R&D costs, which decreased (improving +1.2 percentage points) as productivity savings funded continued investment in the development of differentiated generics; General & Administration costs, which decreased (+1.1 percentage points) due to ongoing cost reduction measures; and Other Income and Expenses, which were positive at 0.5 percentage points due to lower legal fees.

**Consumer Health**

	Q3 2010 USD m	Q3 2009 USD m	% change		9M 2010 USD m	9M 2009 USD m	% change	
			USD	cc			USD	cc
<b>Net sales</b>	<b>1 587</b>	<b>1 476</b>	<b>8</b>	<b>9</b>	<b>4 574</b>	<b>4 189</b>	<b>9</b>	<b>8</b>
<b>Operating income</b>	<b>386</b>	<b>303</b>	<b>27</b>	<b>32</b>	<b>944</b>	<b>809</b>	<b>17</b>	<b>16</b>
As % of net sales	24.3	20.5			20.6	19.3		
<b>Core operating income</b>	<b>410</b>	<b>323</b>	<b>27</b>	<b>30</b>	<b>1 016</b>	<b>870</b>	<b>17</b>	<b>16</b>
As % of net sales	25.8	21.9			22.2	20.8		

**Third quarter****Net sales**

All three Consumer Health businesses – OTC, Animal Health and CIBA Vision – contributed to higher net sales in the third quarter of 2010 (USD 1.6 billion, +8%, +9% cc), as the three businesses continued growing ahead of their respective markets.

Pain medicines were key contributors in OTC. In Europe, *Voltaren* has been a key business driver, becoming the largest self-medication brand in the German market with a year-to-date 44% market share in the topical analgesic market. In the US, *Excedrin* and *Triaminic* are gaining share as a result of solid advertising and promotional campaigns.

*Prevacid24HR* has become a strong competitive brand in the high-growth US Proton Pump Inhibitor (PPI) category. This category has grown 35% year-to-date and *Prevacid24HR* maintained a market share of 20% of the US OTC PPI market in the third quarter. *Pantoloc Control*, the PPI licensed throughout Europe in early 2010, has now been successfully launched as expected in all 14 European markets targeted.

CIBA Vision maintained its growth rate, expanding in all regions driven by sales growth of *AirOptix*, which was among the top performers worldwide in its sector, helping CIBA Vision to increase its share in the global contact lens market to 23%. The US business increased its market share over 3 percentage points to a record 27%, up from just over 23% in 2009.

Animal Health grew ahead of its market in the US, helped by a strong performance of its top brands *Interceptor* and *Sentinel* in the US parasiticides segment and *Milbemax* in key European markets. Cattle vaccines in the US Farm Animal Business have gained share year-to-date, as well.

The US (USD 0.5 billion, +13% cc) delivered a strong performance across all three businesses, while Europe (USD 0.7 billion, +8% cc) achieved robust growth on the leadership of Germany, and Italy. Net sales in the top six emerging markets grew by 12% (+9% cc) to USD 123 million, with a solid single digit growth in Brazil and double-digit growth in the remaining five markets.

**Operating income**

Operating income rose 27% (+32% cc) to USD 386 million, with the operating income margin expanding by 3.8 percentage points in the third quarter of 2010 to 24.3% of net sales.

Core operating income grew 27% (+30% cc) to USD 410 million, with a strong operating leverage, resulting in a growth of the core operating income margin by 3.9 percentage points to 25.8% of net sales. Gross profit margin (69.3% of net sales; +1.7 percentage points) improved as a result of pricing and productivity gains. Marketing & Sales expenses (32.8% of net sales; -0.1 percentage points), increased to support investments for new product launches as well as sales force expansions across all the businesses. Investment in R&D (5.6% of net sales; flat as percentage points) continues to strongly support product development across all Consumer Health businesses. General & Administrative expenses (5.8% of net sales; flat as percentage points) are contributing to the strong operational leverage as a result of productivity actions across all the businesses. Other Income & Expense (0.7% of net sales; +2.3 percentage points) improved as a result of the divestment of a non-core brand in OTC US as well as a one-time expense in the year-ago period.

**Nine months to September 30**

**Net sales**

Sales grew 9% (8% cc) to USD 4.6 billion and all Consumer Health businesses delivered solid growth ahead of their respective markets.

CIBA Vision continues to be the industry's fastest-growing contact lens and lens care company on the strength of *AirOptix* across all the regions. OTC grew on the back of *Excedrin* and *Triaminic* in the US, *Voltaren* in Europe and from the new introductions *Prevacid24HR* and *Pantoloc Control* in the gastrointestinal category. Animal Health growth has been led mainly by a strong performance in *Interceptor* and *Sentinel* in the US and *Milbemax* in Europe, plus good growth of cattle vaccines in the US livestock market.

**Operating income**

Operating income rose 17% (16% cc) to USD 944 million, with the operating income margin improving versus the same period in 2009 by 1.3 percentage points to 20.6% of net sales in 2010.

Core operating income rose 17% (16% cc) to USD 1.0 billion, with strong operating leverage, driving the core operating income margin up by 1.4 percentage points to 22.2% of net sales versus the same period in 2009. Gross profit margin improvements, productivity gains, and income from an OTC US non-core brand divestment have been the growth drivers, partially offset by higher investments in Marketing & Sales to support new product launches and sales force expansions.



**Alcon, Inc.**

	Q3 2010 and 9M 2010 USD m
<b>Net sales</b>	<b>617</b>
<b>Operating income</b>	<b>101</b>
As % of net sales	16.4
<b>Core operating income</b>	<b>222</b>
As % of net sales	36.0

**Third quarter and nine months to September 30****Net sales**

On August 25, 2010, Novartis acquired an additional 52% of Alcon, raising its stake to a 77% controlling interest in Alcon and thereafter has consolidated Alcon's financial results. Sales consolidated for this period amounted to USD 617 million.

**Operating income**

Alcon contributed USD 101 million to Novartis operating income.

This amount includes an additional charge of USD 95 million relating to the estimated fair value revaluation of inventory as of the change in majority ownership date; USD 7 million amortization of intangible assets and USD 19 million of costs resulting from the change in majority ownership.

Excluding these items, core operating income totaled USD 222 million.

**FINANCIAL REVIEW****Third quarter and nine months to September 30**

	Q3 2010	Q3 2009	% change		9M 2010	9M 2009	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>12 578</b>	<b>11 086</b>	<b>13</b>	<b>16</b>	<b>36 425</b>	<b>31 341</b>	<b>16</b>	<b>15</b>
Divisional operating income	2 814	2 849	-1	3	9 432	7 934	19	18
Corporate income & expense, net	-227	-215	6	4	-373	-589	-37	-37
<b>Group operating income</b>	<b>2 587</b>	<b>2 634</b>	<b>-2</b>	<b>3</b>	<b>9 059</b>	<b>7 345</b>	<b>23</b>	<b>23</b>
<i>as % of net sales</i>	20.6	23.8			24.9	23.4		
Income from associated companies	368	-21	nm		629	186	238	
Financial income	27	51	-47		90	94	-4	
Interest expense	-188	-173	9		-496	-395	26	
Taxes	-475	-379	25		-1 578	-1 099	44	
<b>Net income</b>	<b>2 319</b>	<b>2 112</b>	<b>10</b>	<b>14</b>	<b>7 704</b>	<b>6 131</b>	<b>26</b>	<b>24</b>
<b>EPS (USD)</b>	<b>0.99</b>	<b>0.93</b>	<b>6</b>	<b>12</b>	<b>3.34</b>	<b>2.69</b>	<b>24</b>	<b>22</b>
<b>Core operating income</b>	<b>3 699</b>	<b>2 959</b>	<b>25</b>	<b>29</b>	<b>10 840</b>	<b>8 233</b>	<b>32</b>	<b>31</b>
<i>as % of net sales</i>	29.4	26.7			29.8	26.3		
<b>Core net income</b>	<b>3 146</b>	<b>2 679</b>	<b>17</b>	<b>21</b>	<b>9 226</b>	<b>7 375</b>	<b>25</b>	<b>24</b>
<b>Core EPS (USD)</b>	<b>1.36</b>	<b>1.17</b>	<b>16</b>	<b>19</b>	<b>4.00</b>	<b>3.24</b>	<b>23</b>	<b>22</b>

nm Not meaningful

**Third quarter and nine months to September 30 excluding Alcon, Inc.**

	Q3 2010	Q3 2009	% change		9M 2010	9M2009	% change	
	USD m	USD m	USD	cc	USD m	USD m	USD	cc
<b>Net sales</b>	<b>11 961</b>	11 086	8	10	<b>35 808</b>	31 341	14	13
<b>Operating income</b>	<b>2 582</b>	2 634	-2	3	<b>9 054</b>	7 345	23	23
<i>as % of net sales</i>	21.6	23.8			25.3	23.4		
<b>Core operating income</b>	<b>3 477</b>	<b>2 959</b>	<b>18</b>	<b>22</b>	<b>10 618</b>	<b>8 233</b>	<b>29</b>	<b>28</b>
<i>as % of net sales</i>	29.1	26.7			29.7	26.3		

**Third quarter****Net sales**

Net sales rose 13% (+16% cc) to USD 12.6 billion with strong contributions from all businesses. Currency movements depressed the result by 3 percentage points. Rapid growth of recently launched products across the Group generated USD 2.3 billion in sales, representing 20%\* of total sales. Acquisitions contributed 6 percentage points to growth, mainly driven by the Alcon sales of USD 617 million. Volumes grew by 11 percentage points offset by a negative price effect of 1 percentage point.

**Corporate income & expense, net**

Corporate income & expense, which includes the costs of the Group headquarters and costs for corporate research, was impacted by one-time stamp duty and transaction expenses related to the purchase of the additional 52% of Alcon shares of USD 96 million in the third quarter. Excluding this, expenses were 39% below the previous year partially as a result of releasing USD 38 million of environmental and other provisions.

**Group operating income**

Operating income decreased 2% (+3% cc) to USD 2.6 billion. Currency movements, particularly the strengthening Swiss franc, which increases costs, reduced operating income by 5 percentage points. Included in operating income are intangible asset impairment charges in R&D expenses of USD 593 million principally due to the termination of two development projects, and Alcon related charges of USD 217 million.

**Income from associated companies**

The income from associated companies in the third quarter of 2010 of USD 368 million compares to a net loss of USD 21 million in 2009. Alcon, Inc, accounted for as an associated company until August 25, and thereafter fully consolidated, contributed USD 235 million compared to a loss of USD 62 million in the prior year period. Included in this total is a revaluation gain of USD 204 million to the currently estimated fair value of the initial 25% Alcon, Inc interest acquired on July 7, 2008, required as a result of acquiring majority control on August 25, 2010. 2009 included an exceptional impairment charge of USD 92 million. The Roche investment contributed USD 138 million in the third quarter compared to USD 43 million in the prior year period which was impacted by a restructuring charge of USD 97 million related to the Genentech acquisition. The following is a summary of the individual components included in the income from associated companies:

	Q3 2010 USD m	Q3 2009 USD m	9M 2010 USD m	9M 2009 USD m
Share of estimated Roche reported net income	173	176	480	461
Catch-up for actual Roche previous year net income				-40
Genentech restructuring impact		-97	-43	-97
Amortization of intangible assets	-35	-36	-101	-98
<b>Net income effect from Roche</b>	<b>138</b>	<b>43</b>	<b>336</b>	<b>226</b>
Share of Alcon, Inc reported US GAAP net income	118	139	400	368
Catch-up for actual up to August 25, 2010 Alcon, Inc net income	-15		-13	5
Revaluation of initial 25% interest to estimated deemed fair value	204		204	
Intangible asset impairment charge		-92		-92
Amortization of intangible assets	-72	-109	-289	-326
<b>Net income effect from Alcon, Inc up to August 25, 2010</b>	<b>235</b>	<b>-62</b>	<b>302</b>	<b>-45</b>
Net income from other associated companies	-5	-2	-9	5
<b>Income from associated companies</b>	<b>368</b>	<b>-21</b>	<b>629</b>	<b>186</b>

Core results for associated companies for the third quarter, which exclude exceptional items and the amortization of intangible assets in both periods, decreased from USD 313 million in the 2009 third quarter to USD 286 million in the current year quarter.

**Financial income and interest expense**

Financial income decreased from USD 51 million in third quarter of 2009 to USD 27 million in the current third quarter as lower returns on financial investments outweigh the improved currency result. Interest expense increased from USD 173 million to USD 188 million due to the additional fund-raising.

**Taxes**

The tax rate (taxes as percentage of pre-tax income) was 17.0% in the third quarter compared to 15.2% in the 2009 period.

**Net income**

Net income advanced 10% (+14% cc) to USD 2.3 billion ahead of operating income growth. Core net income grew 17% (+21%) to USD 3.1 billion.

**Earnings per share**

Earnings per share (EPS) rose 6% (+12% cc) to USD 0.99 from USD 0.93 in the 2009 period while core EPS was up 16% (+19% cc) to USD 1.36 from USD 1.17 in the year-ago period. The increase in EPS is less than the increase in net income due to 23% of the net income related to Alcon being excluded from the EPS calculation.

The average number of shares outstanding in the third quarter rose 1% to 2,288.1 million from 2,268.2 million in the year-ago period while a total of 2,289.6 million shares were outstanding at September 30.

**Nine months to September 30**

**Net sales**

Net sales were up 16% (+15% cc) to USD 36.4 billion with strong improvements across all businesses. Recently launched products provided USD 7.9 billion (versus USD 4.3 billion in the previous year-period), contributing 22%\* of total sales. Volumes grew by 13 percentage points and price contributed a negative 1 percentage point for the nine months period. Acquisitions contributed 3 percentage points to growth, mainly driven by Alcon sales of USD 617 million.

**Group operating income**

Operating income rose 23% (+23% cc) to USD 9.1 billion on the volume-driven sales expansion and by contributions of A(H1N1) pandemic flu vaccines. The operating income margin improved 1.5 percentage points to 24.9% of net sales from 23.4% in the 2009 period. Included in operating income are exceptional charges including intangible asset impairments charged to R&D (USD 762 million) and legal settlements (USD 237 million), offset by a pension gain of USD 265 million.

**Income from associated companies**

The income from associated companies for the nine-month period of 2010 increased from USD 186 million to USD 629 million. The increase is attributable to higher contributions from the Alcon and Roche investments due to exceptional charges incurred in the prior year period as well as the revaluation gain to the currently estimated fair value of the initial 25% Alcon interest acquired on July 7, 2008.

Core results for associated companies, excluding the exceptional charges due to the Genentech restructuring for Roche and the intangible impairment charge and revaluation gain for Alcon as well as the amortization of intangible assets for both investments, increased from USD 799 million to USD 873 million.

**Financial income and interest expense**

Financial income decreased by 4% from USD 94 million to USD 90 million. In order to accommodate the payment for the Alcon acquisition financial investments were kept short-term which resulted in lower yields. Interest expense increased by 26% to USD 496 million from USD 395 million in the prior year period as a result of the issuance of US dollar bonds in February 2009 and March 2010, a Euro bond in June 2009 and the increase of short-term debts through the commercial paper program.

**Taxes**

The tax rate (taxes as percentage of pre-tax income) was 17.0% in the first nine months of 2010 compared to 15.2% in the 2009 period.

### **Net income**

Net income advanced 26% (+24% cc) to USD 7.7 billion ahead of operating income growth. Core net income grew 25% (+24% cc) to USD 9.2 billion.

### **Earnings per share**

Earnings per share (EPS) rose largely in line with net income to USD 3.34 from USD 2.69 in the 2009 period, while core EPS grew 23% (+22% cc) to USD 4.00 from USD 3.24. The average number of shares outstanding in the first nine months 2010 rose 1% to 2,284.4 million from 2,266.2 million in the year-ago period, while a total of 2,289.6 million shares were outstanding at September 30.

### **Balance sheet**

The full consolidation of Alcon has had a significant impact on the Group's consolidated balance sheet. Non-current assets have increased by USD 35.1 billion since December 31, 2009, of which the major items result from the preliminary purchase price allocation for the Alcon acquisition, which increased identified intangible assets by USD 24.2 billion and goodwill by USD 18.1 billion. Furthermore, there was a reduction in the amount of investments in associated companies (included in financial and other non-current assets) by USD 10.1 billion. Current assets decreased by USD 6.0 billion mainly due to USD 9.5 billion lower cash and marketable securities as these funds were used to acquire the additional 52% of Alcon. Trade accounts receivable, inventories and other current assets increased by USD 3.5 billion also mainly due to the consolidation of Alcon. As a result of the consolidation of Alcon and other factors, total assets amounted to USD 124.6 billion at September 30, 2010, an increase of USD 29.1 billion compared to the end of 2009.

Similarly, the consolidation of Alcon and related financing for the additional 52% interest has had a significant impact on the Group's liabilities and equity. Financial debts increased by USD 13.0 billion, which was mainly used to fund the Alcon acquisition. Other current and non-current liabilities increased by USD 7.4 billion of which USD 4.4 billion are additional deferred tax liabilities primarily related to the Alcon identified intangible assets. Principally due to these factors, total liabilities increased by USD 20.4 billion to USD 58.4 billion at September 30, 2010. The Group's equity rose by USD 8.8 billion since the prior year-end to USD 66.2 billion at September 30, and includes the 23% Alcon additional non-controlling interests of USD 6.1 billion. Other movements in equity were the net income of USD 7.7 billion, which was partially offset by the dividend payment for 2009 of USD 4.5 billion and actuarial losses of USD 1.4 billion. An additional increase of USD 1.0 billion was due to the net sale of treasury shares and share-based compensation as well as positive translation effects.

The Group's debt/equity ratio rose to 0.41:1 at September 30, compared to 0.24:1 at the end of 2009, reflecting the higher financial debt for the funding of the Alcon acquisition. The Group's financial debt of USD 27.0 billion consisted of USD 12.6 billion in current and USD 14.4 billion in non-current liabilities. Overall liquidity, including USD 3.2 billion consolidated with Alcon, decreased to USD 8.0 billion from USD 17.4 billion at the end of 2009. Net debt at September 30 was USD 19.0 billion compared to net liquidity of USD 3.5 billion at the end of the previous year.

#### **Cash flow**

Cash flow from operating activities for the first nine months rose USD 1.8 billion to USD 9.5 billion based on higher earnings from operations.

The cash flow from investing activities resulted in a net outflow of USD 15.2 billion in 2010. The outflow for acquisitions was USD 26.7 billion. This amount comprised USD 26.1 billion (net of USD 2.2 billion cash received) for the purchase of the additional 52% investment in Alcon and USD 0.5 billion for the acquisition of Corthera, Oriol and for deferred payments related to the EBEWE acquisition. The outflow of cash for investments in property, plant & equipment and in intangible and other assets amounted to USD 1.0 billion and USD 0.5 billion respectively. These outflows were partially compensated by the net inflow from the sale of marketable securities of USD 12.8 billion.

Cash inflow from financing activities was USD 8.2 billion as the USD 12.3 billion proceeds from the bonds and the commercial paper programs were partially offset by the dividend payment of USD 4.5 billion.

Free cash flow before dividends rose 34% to USD 8.2 billion, the increase principally coming from the improved cash flow from operating activities.



**INNOVATION REVIEW**

Novartis has one of the industry's most competitive pipelines with 143 projects in pharmaceutical clinical development, of which 56 involve new molecular entities.

Among developments in the third quarter of 2010:

- The FDA approved *Gilenya*, a novel, first-line oral treatment for relapsing forms of multiple sclerosis – the most common forms of the disease. The drug has been shown previously to significantly reduce the relapse rate compared to intra-muscular interferon beta 1a, the current standard of care, and also to delay disability progression versus placebo. Moreover, *Gilenya* has a well-studied safety and tolerability profile that has been characterized in over 2,600 clinical trial patients.
- The CHMP gave a positive opinion for the approval of *Tasigna* for the treatment of newly diagnosed patients with chronic myeloid leukemia (CML). The formal EMA approval is expected by the end of this year. *Tasigna* is already approved in the US and Switzerland, for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. Regulatory submissions in the first-line indication have also been submitted in Japan and other countries around the world.
- The FDA approved *Tekamlo* (aliskiren and amlodipine) tablets, a single-pill combination for the treatment of high blood pressure combining the only approved direct renin inhibitor, *Tekturna* (aliskiren), with the widely used calcium channel blocker, amlodipine. *Tekamlo* has been shown to significantly reduce blood pressure as compared to amlodipine or *Tekturna* alone.
- The CHMP gave a positive opinion for the approval of tobramycin inhalation powder (*TOBI Podhaler*) for the suppressive therapy of chronic pulmonary infection due to *Pseudomonas aeruginosa* in adult and children age six years and older with cystic fibrosis. Formal EMA approval is expected by the end of this year.
- Submission for US approval of *Diovan* (valsartan) for the prevention of new onset diabetes in hypertensive patients with impaired glucose tolerance and increased cardiovascular risk was achieved in July.
- SOM230 (pasireotide) demonstrated significant efficacy in a Phase III trial in reducing the level of urinary free cortisol (UFC) in patients suffering from Cushing's disease, a potentially fatal and debilitating hormonal disorder. This pivotal trial is the largest study to date of a medical therapy in Cushing's disease.
- A dossier for EU approval of *Afinitor* (everolimus) in patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis was also filed in July 2010; the FDA granted everolimus priority review for this indication. The FDA action date is October 29.

- Results from a Phase III study involving *Afinitor* in pancreatic neuroendocrine tumors (NET), a rare and aggressive form of cancer with limited treatment options, showed that *Afinitor* extended median progression-free survival from 4.6 to 11 months versus placebo and reduced the risk of cancer progression by 65%. The results of this study, RADIANT-3, were shared at World Congress of Gastrointestinal Cancer (WCGI) on July 1, 2010.
- Results from the Phase III RADIANT-2 study showed *Afinitor* plus *Sandostatin LAR* extended time without tumor growth from 11.3 to 16.4 months when compared to *Sandostatin LAR* alone in patients with advanced neuroendocrine tumors (hazard ratio=0.77 [95% confidence interval, 0.59 to 1.00]; p=0.026). The study did not meet the primary endpoint of progression-free survival. Analyses using a well-established statistical model to adjust for imbalances in the treatment arm showed *Afinitor* plus *Sandostatin LAR* significantly reduced risk of disease progression.
- The Phase III study examining AIN457 for non-infectious uveitis in patients with Behcet's disease did not meet its primary endpoint and the data do not support submission of AIN457 for this indication. Based upon analysis of these data, Novartis will stop the extension study in Behcet's uveitis while continuing to explore other indications.
- Novartis decided to discontinue further development of *Mycograb* (efungumab), an antifungal agent that was being developed for invasive candidiasis in adult patients. Novartis and Human Genome Sciences also agreed to stop further development of albinterferon alfa-2b for the treatment of chronic hepatitis C viral infection. Further development of QAX028 in chronic obstructive pulmonary disease (COPD) was also discontinued in August. These decisions reflect the enhanced focus on portfolio prioritization and productivity within the company.
- Top line Phase III results (Study 2301) from SMC021 in osteoarthritis did not meet the first of three co-primary endpoints. Further analysis of the data is ongoing. The Phase III study in osteoporosis continues.

## Q3 2010 selected major approvals: US, Europe and Japan

Product	Active ingredient	Indication	Approval date
<i>Gilenya</i>	fingolimod	Multiple sclerosis	US September
<i>Tekamlo</i>	aliskiren,amlodipine	Hypertension	US - August

## Selected projects awaiting regulatory decisions

Product	Indication	US	Completed submissions	Japan	News update
<i>Afinitor</i>	Subependymal giant cell astrocytomas associated with tuberous sclerosis	Q2 2010	EU Q3 2010		- EU filing achieved in July  - US approval expected by end of 2010 based on priority review status
<i>Diovan</i>	Prevention of new onset diabetes	Q3 2010			- US filing achieved in July
<i>Exelon Patch</i>	Alzheimer s disease dementia	Approved	Approved	Q1 2010	- New drug application in Japan (NDA-J) is under review. Pharmaceuticals and Medical Devices Agency (PMDA) decision may come as early as April 2011
<i>Gilenya</i>	Multiple sclerosis	Approved	Q4 2009		- FDA approval received in September with first-line indication for relapsing forms of multiple sclerosis  - The European Medicines Agency (EMA) regulatory review and other filings worldwide are ongoing
<i>Lucentis</i>	Diabetic macular edema		Q4 2009		- Phase III RESTORE data presented in May 2010 at the European Association for the Study of Diabetic Eye Complications  - Regulatory feedback expected in Q4 2010
<i>Onbrez</i>	Chronic obstructive pulmonary disease	Q4 2008	Approved	Q3 2010	- Clinical trials to address US Food and Drug Administration (FDA) complete response letter (October 2009) completed in Q3 and data generated from these trials was submitted to the FDA in late September
<i>Tasigna</i>	Newly diagnosed chronic myeloid leukemia	Approved	Q4 2009	Q1 2010	- Japan filing achieved in July - Positive Committee for Medicinal Products for Human Use (CHMP) opinion received

				in September
				- Swiss approval in August after fast-track review
				- ENESTnd 24 month median follow-up data expected to be presented at the American Society of Hematology in December
<i>Tekturna</i> and amlodipine	Hypertension	Approved	Q4 2009	- FDA approval received in August
				- EU CHMP opinion expected in Q1 2011 and formal approval in Q2 2011
<i>Tekturna</i> , amlodipine and Hydro-chlorothiazide	Hypertension	Q1 2010	Q2 2010	- Application of Rasival withdrawn from EMA - EU submission achieved in May 2010
<i>TOBI Podhaler</i>	Cystic fibrosis		Q4 2009	- Positive CHMP opinion received in September

Product	Indication	US	Completed submissions		Japan	News update
			EU			
<i>Zometa</i>	Adjuvant breast cancer	Q4 2009	Q4 2009			- FDA extended the review of sNDA of Zometa in the adjuvant (post-surgery) treatment of premenopausal women with early breast cancer in conjunction with hormonal therapy from Q4 2010 to Q1 2011. Extension is the result of a major amendment to the application to include an additional 12 months of data to provide a median of five years of follow up of the pivotal Austrian Breast & Colorectal Cancer Study Group Trial 12 (ABCSG-12) study. This information has also been submitted to European regulatory authorities.

## Selected pharmaceutical pipeline projects

Project/Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
ACZ885	Refractory gout acute flares	2010	III	- On track for 2010 submission
	Systemic onset juvenile idiopathic arthritis	2011	III	
	Type 2 diabetes	≥2014	II	
	Secondary prevention of cardiovascular events	≥2014	III	- Phase III start planned end 2010
<i>Afinitor</i>	Neuroendocrine tumors	2010	III	- On track for 2010 submission - RADIANT 3 study in pancreatic neuroendocrine tumors (NET) met primary endpoint; results shared at World Congress of Gastrointestinal Cancer in July 2010 - RADIANT-2 study did not meet the primary endpoint of progression-free survival. Analyses using a well-established statistical model to adjust for imbalances in the treatment arm showed <i>Afinitor</i> plus <i>Sandostatin LAR</i> significantly reduced risk of disease progression - Results of RADIANT-2 and RADIANT-3 were shared at the European Society for Medical Oncology in October 2010
	Tuberous sclerosis	2011	III	
	complex AML			
	ER+ breast cancer	2012	III	
	HER2+ breast cancer	2013	III	
	Gastric cancer	2012	III	
	HCC (Hepatocellular cancer)	2013	III	
	Lymphoma	≥2014	III	
	AfQ056	Parkinson's disease- L-dopa induced dyskinesia	2013	II

Fragile X syndrome

2012

II

- Adult pivotal study to start 4Q 2010

Edgar Filing: NOVARTIS AG - Form 6-K

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
AG0178	Major depressive disorder	2012	III	- Sublingual Phase III program initiated May 2010
AIN457	Non-infectious uveitis	2011	III	- Phase III study examining AIN457 for non-infectious uveitis in patients with Behcet's disease did not meet its primary endpoint and the data do not support submission of AIN457 for this indication; based upon analysis of these data, Novartis will stop the extension study in Behcet's uveitis
	Psoriasis	2013	II	- Phase III start planned for 2011
	Rheumatoid arthritis	2013	II	- Phase III start planned for 2011
ASA404	2nd line non-small cell lung cancer	2012	III	- Interim analysis in Q4 2010
BAF312	Multiple sclerosis	≥2014	II	- Phase II data expected in Q1 2011
<i>Certican</i>	Prevention of organ rejection liver	2011	III	
DEB025	Hepatitis C	2013	II	- Phase III start planned in Q4 2010
<i>Exjade</i>	Non transfusion dependent Thalassemia	2011	II	
HCD122	Hematological tumors	≥2014	I	
INC424	Myelofibrosis	2011	III	- Results from a Phase I/II study published in <i>The New England Journal of Medicine</i> in September showed approximately 75% of myelofibrosis patients receiving INC424 twice-daily experienced rapid reduction in spleen size, which was durable for more than one year of follow-up
	Polycythemia vera	≥2014	II	- Global Phase III study expected to begin in October with US patients; first ex-US patient study expected to start in Q1 2011
LBH589	Hodgkin's lymphoma	2010	III	- On track for 2010 submission - Updated Phase II pivotal study data presented at the American Society of Clinical Oncology and European Hematology Association congresses
	Multiple myeloma	2013	III	- Phase I data oral LBH589 in combination with Velcade (bortezomib) presentation at American Society of Clinical Oncology
	Hematological tumors	≥2014	II	
LCQ908	Diabetes and metabolism	≥2014	II	
LCZ696	Heart failure	≥2014	III	- Phase II data published in <i>Lancet</i> and presented at the American College of Cardiology in March 2010. Demonstrated blood pressure lowering and supports heart failure potential. - Phase III M&M study ongoing since Dec 2009
	Hypertension	≥2014	II	
LDE225	Gorlin's syndrome	2012	II	
<i>Lucentis</i>	Retinal vein occlusion	2010	III	- EU submission on track for Q4 2010

Edgar Filing: NOVARTIS AG - Form 6-K

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
NVA237	Chronic obstructive pulmonary disease	2011	III	
PKC412	Aggressive systemic mastocytosis	2011	II	
PRT128	Acute myeloid leukemia	2013	III	
	Acute coronary syndrome	≥2014	II	- Results from INNOVATE-PCI Phase II study were presented at the European Society of Cardiology congress in August 2010. Planned to initiate a Phase III clinical development program in chronic coronary heart disease in Q1 2011
PTK796	Chronic coronary heart disease			
PTK796	Complicated skin and soft tissue infections	2012	III	
QMF149	Chronic obstructive pulmonary disease	≥2014	II	- Filing now planned for ≥2014. Delay due to device switch to Concept 1
	Asthma	≥2014	II	- Filing now planned for ≥2014. Delay due to device switch to Concept 1
QTI571 (Imatinib)	Pulmonary arterial hypertension	2011	III	
QVA149	Chronic obstructive pulmonary disease	2012	III	
RLX030	Acute heart failure	2013	III	
SMC021	Osteoarthritis	2011	III	- Top line Phase III results (Study 2301) from SMC021 in osteoarthritis did not meet the first of three co-primary endpoints - Further analysis of the data is ongoing.
	Osteoporosis	2011	III	- On track for 2011 submission. - Blinded two-year interim analysis expected end 2010
SOM230	Cushing's disease	2010	III	- On track for 2010 submission in EU and H1 2011 in US - Phase III study met endpoint in patients taking SOM230 900 µg; results presented at the European Neuroendocrine Association in September
	Acromegaly	2011	III	
	Refractory / resistant carcinoid syndrome	2011	III	
<i>Tasigna</i>	Gastrointestinal stromal tumor	≥2014	III	
	cKIT melanoma	2012	III	
TKI258	Solid tumors	2013	II	
<i>Xolair</i>	Chronic idiopathic urticaria	2013	II	- Phase III planned to start in Q1 2011



## Selected vaccine pipeline projects

Project/ Compound	Potential indication/ Disease area	Planned submissions	Current Phase	News update
<i>Menveo</i>	Prevention of meningococcal disease (serogroups A, C, Y and W-135) in infants	2010 (US) 2011 (EU)	III	US filing planned Q4 2010
<i>MenB</i> (meningococcal serogroups B)	Multi-component vaccine for prevention of meningococcal disease (serogroup B)	2010 (EU)	III	- Results from initial Phase III study presented in September at International Pathogenic Neisseria Conference  - EU submission planned to be filed by year-end
<i>Optaflu</i>	Seasonal influenza (cell culture subunit vaccine)	2011 (US)	III	
<i>Fluad</i>	Seasonal influenza (subunit vaccine with MF59 adjuvant)	2010 (EU) 2012 (elderly US)	III	- Trial results to be published at Infectious Diseases Society of America in October 2010  - Phase III trial started

## Disclaimer

These materials contain certain forward-looking statements relating to the Group's business, which can be identified by terminology such as pipeline, momentum, prospects, potential, commitment, strategic, priorities, recommendation, promise, will, on track, pro expected, opportunities, outlook, guidance, priority review, preparing for filing, planned, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products, or potential future sales or earnings of the Novartis Group or any of its divisions, business units, or consolidated entities; or regarding potential growth opportunities from the acquisition of a 77% majority ownership in Alcon or regarding the potential full acquisition and merger with Alcon; 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 existing products in any market, or that such products will achieve any particular revenue levels. Nor can there be any guarantee that the Novartis Group, or any of its divisions, business units, or consolidated entities will achieve any particular financial results. Neither can there be any guarantee that the proposed full acquisition and merger with Alcon will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Novartis will be able to realize any of the potential synergies, strategic benefits or opportunities as a result of either Novartis' acquisition of a 77% majority ownership in Alcon, or as a result of the proposed full acquisition and merger with Alcon. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; the Group's ability to obtain or maintain patent or other proprietary intellectual property protection; disruptions from the Alcon 77% implementation, and any potential merger making it more difficult to maintain business and operational relationships, and relationships with key employees; uncertainties regarding actual or potential legal proceedings, including, among others, litigation seeking to prevent the full acquisition and merger from taking place, product liability litigation, litigation regarding sales and marketing practices, government investigations and intellectual property disputes; competition in general; government, industry, and general public pricing and other political pressures; 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 pharmaceutical 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 these materials 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 healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## Important dates

November 17, 2010	Novartis Strategy and Innovation Forum
January 27, 2011	Fourth quarter and full-year 2010 results



**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: October 21, 2010

By: /s/ MALCOLM B. CHEETHAM

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