

NOVARTIS AG  
Form 6-K  
February 07, 2006

# 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 for January 2006

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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

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Form 20-F: ☒ Form 40-F: ☐

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Yes: ☐ No: ☒

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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: ☒

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Enclosures:

1. Sandoz Welcomes CHMP Positive Opinion on Omnitrope (Holzkirchen, Germany, January 27, 2006)
2. Novartis accelerates production of life-saving malaria treatment *Coartem*® (Basel, January 18, 2006)
3. Novartis Venture Fund to expand role in 2006 in supporting pharmaceutical start-up companies (Basel, January 16, 2006)
4. Novartis decides not to make offer to acquire Berna Biotech (Basel, January 10, 2006)

**MEDIA RELEASE      COMMUNIQUE AUX MEDIAS      MEDIENMITTEILUNG**

**Sandoz Welcomes CHMP Positive Opinion on Omnitrope**

**Holzkirchen, Germany, January 27, 2006** Sandoz welcomes the positive opinion issued by the European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) regarding the company's recombinant human growth hormone Omnitrope.

The positive CHMP opinion for Omnitrope is an important step on the way to make this medicine available for patients who need it, said Dr. Andreas Rummelt, CEO Sandoz. Omnitrope will contribute to cost savings in the Health Care systems and we are confident that the European Commission will now grant marketing authorization.

In June 2003, the CPMP (as the Committee was named at that time) recommended that the European Commission grant Marketing Authorization for Omnitrope, but the Commission refused the Marketing Authorization on legal grounds related to the selected approval pathway. Sandoz submitted a second application in July 2004, based on a recommendation from the European Medicines Agency (EMA) and the Commission. This application followed the new Annex to Directive 2001/83/EC as amended and published with directive 2003/63/EC, which provided a pathway for these products.

Australia's Therapeutic Goods Administration approved Omnitrope in September 2004 for treatment of growth disorders in children. The product was launched in Australia in November 2005.

In the U.S., the Food and Drug Administration notified Sandoz in August 2004, that it was unable to reach a decision on whether to approve the company's application for Omnitrope. In September 2005, Sandoz filed a lawsuit against the US Food and Drug Administration, seeking a ruling on its pending application. That lawsuit is still pending.

With Omnitrope's positive status in Europe, we now hope the FDA will finally move in granting a marketing authorization for the US, acknowledging the sound science that supports this product, said Rummelt. We are determined to make high-quality and cost-effective biosimilar products like Omnitrope available for patients and healthcare providers worldwide.

About Sandoz

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Sandoz, a Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, cost-efficient products that are no longer protected by patents. Sandoz has a portfolio of more than 600 active substances in over 5 000 forms worldwide. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these drugs along with pharmaceutical and biotechnological active substances and Anti-Infectives. In addition to the strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and EonLabs (U.S.) and sells its products in more than 110 countries. In 2005, Sandoz employed around 20,000 people worldwide and posted sales of USD 4.7 billion.

This release contains certain forward-looking statements relating to the Group's business, which can be identified by the use of forward-looking terminology, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks referred to in Novartis AG's 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.

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**MEDIA RELEASE      COMMUNIQUE AUX MEDIAS      MEDIENMITTEILUNG**

**Novartis accelerates production of life-saving malaria treatment *Coartem*®**

Novartis produced 30 million treatments in 2005 and is on target to more than triple this number of treatments in 2006

**Basel, January 18, 2006** Novartis announced today that it is on track to produce 100 million treatment courses of its anti-malarial *Coartem* (artemether/lumefantrine) in 2006 (up from 30 million in 2005) if orders are placed by malaria-endemic developing countries in a timely manner. *Coartem* is the only pre-qualified, fixed-dose artemisinin-based combination therapy (ACT) and achieves cure rates of up to 95%.

Reflecting its commitment to helping patients who are suffering from malaria, Novartis continues to provide *Coartem* at cost for public sector use in developing countries where the disease is endemic. Novartis received orders for 14 million *Coartem* treatments for delivery in 2005.

Our production people worked 24 hours per day, seven days a week, in order to get this medicine to as many patients as possible in 2005. Malaria-endemic countries can place orders for *Coartem* confident that Novartis has taken all the necessary steps to sustain supply of this life-saving drug, said Dr. Daniel Vasella, Chairman and CEO of Novartis.

To achieve the unprecedented scale-up in production, the company invested heavily in expanding production capacity at state-of-the-art manufacturing facilities in Beijing, China and Suffern, New York, as well as extending the supply agreements to procure raw materials and active ingredients in Africa and China. The two Chinese firms that manufacture the active ingredients Kunming Pharmaceutical Corporation (KPC) which provides artemether, and Zhejiang Medicine Company (ZMC) which provides lumefantrine recently completed major capacity-expansion programs to help insure continued supply of *Coartem*.



Having adequate supply of ACTs like *Coartem* and getting this life-saving medicine to those in need is central to our fight against malaria, said Dr. Fred Binka, Associate Professor of Epidemiology at the School of Public Health, University of Ghana, and Executive Director of the INDEPTH Network, based in Accra, Ghana. We applaud efforts by Novartis to dramatically increase the supply so that more patients can benefit from this important therapy.

With a cure rate of above 95% and very few side effects, *Coartem* clears parasites from the blood faster than other non-artemisinin anti-malaria drugs, also helping to reduce the transmission of the disease. In some regions of Africa, the number of malaria cases has dropped by more than 90% when ACTs were used in combination with other malaria control measures.

We have seen much success from our malaria control efforts in Zambia, including the nationwide usage of *Coartem* in the public sector, said Dr. Naawa Sipilanyambe, Coordinator of the country's National Malaria Control Program. We have witnessed a 10.5% drop in malaria incidences in 2004 as compared to 2003, and a decline in malaria deaths from 50,000 to 33,000 over the same time period, added Dr. Sipilanyambe.

At Macha Mission Hospital in rural Zambia, pediatric malaria cases were reduced by 90% over the past three years. Data from the children's ward at the hospital show that in the malaria season of 2001-2002, there were 1,517 children discharged with malaria, compared to only 159 children in the 2004-2005 malaria season, said Dr. Philip Thuma, Senior Associate, Johns Hopkins Bloomberg School of Public Health and Director, Malaria Institute at Macha (MIAM) based in Zambia. In addition, the malaria case fatalities recorded for the same two periods went from 52 to only 7 which is an 87% reduction.

#### **About malaria**

Worldwide, experts estimate that there are between 300 and 500 million new cases of malaria each year, resulting in over one million deaths annually, 90% of which occur in children in Africa. Malaria morbidity and mortality rates are rising in developing countries, largely due to the emergence of drug resistant parasites rendering traditional antimalarial drugs, such as chloroquine and sulfadoxine pyrimethamine (SP) ineffective.

In addition to the devastating toll malaria takes on human life in terms of morbidity and mortality, the disease also has substantial negative impacts on the economic development of nations in which the disease is endemic. The drain on African economies alone is estimated to be USD 12 billion each year (WHO, 2000) and the threat of malaria can be a serious deterrent to tourism, further hampering economic development and growth.

#### **About *Coartem***

*Coartem* is the only pre-qualified, fixed-dose ACT combining artemether, an artemisinin derivative, and lumefantrine. It is a highly effective and well-tolerated antimalarial that achieves cure rates of up to 95%, even in areas of multi-drug resistance. It is indicated for the treatment of acute uncomplicated falciparum malaria, the most dangerous form of malaria. The company provides a three-day treatment regimen of *Coartem* for adults and children at cost through the public market for a price of USD 2.40 and USD 0.90, respectively.

Artemisinin is a compound derived from the sweet wormwood plant and has been used for centuries in traditional Chinese medicine to treat fever. An artemisinin-based combination therapy is a combination of two or more drugs (one of which is an artemisinin derivative) that have different modes of action and different targets. Studies have shown that using two or more drugs in combination has the potential to delay the development of resistance in areas of low transmission. Artemisinin-based combination therapies in particular have been found to be highly effective in treating malaria and their potential to delay resistance in areas of intense transmission is under investigation.

*Coartem* was co-developed by Novartis in collaboration with Chinese partners who also supply the active ingredients (artemether and lumefantrine) and is produced in China and the U.S. by Novartis. *Coartem* is currently registered in 75 countries worldwide and more than 17 million treatment courses have been supplied to the public sector of malaria-endemic developing countries since 2001. *Coartem* has been extensively studied in multi-center clinical trials involving more than 3,000 patients.



The supply chain for manufacturing ACTs is particularly complex and time-consuming. Artemether, one of the active ingredients in *Coartem*, is derived from artemisinin which is the starting material for all ACTs. Artemisinin is a plant derived raw material and crops of *Artemisia annua* must be planted one growing season ahead of harvesting and extraction for use in production. The cultivation of *Artemisia annua* requires a minimum of seven months. The entire process of making *Coartem* takes approximately 14 months from planting of seeds to final production of the medicine.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "on target", "on track", or similar expressions, or by express or implied discussions regarding Novartis' ability to satisfy *Coartem* production requirements in 2006 or the future. Such forward looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause the actual results with *Coartem* to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Novartis will be able to achieve any particular level of *Coartem* production in the future. Any such results can be affected by, among other things, uncertainties regarding the timeliness of the orders to be placed for *Coartem* by the ordering countries, uncertainties regarding the ability to obtain the necessary raw materials, uncertainties relating to the performance of our suppliers KPC and ZMC, uncertainties relating to regulatory actions or government regulation generally, including Good Manufacturing Practices Regulations, as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group's businesses achieved net sales of USD 28.2 billion and pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.1 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 91,700 people and operate in over 140 countries around the world.

For further information please consult <http://www.novartis.com>.

Novartis was recently honored with the 2005 Excellence in Corporate Philanthropy Award from the Committee to Encourage Corporate Philanthropy. In 2004, over 4.25 million patients around the world benefited from Novartis programs valued at USD 570 million. These initiatives range from drug donation and research programs to combat neglected diseases like malaria, tuberculosis and leprosy in developing nations to patient assistance programs that help cancer patients receive the most innovative and effective treatments available. For further information please consult <http://www.novartis.com>.

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**MEDIA RELEASE**

**COMMUNIQUE AUX MEDIAS**

**MEDIENMITTEILUNG**

**Novartis Venture Fund to expand role in 2006 in supporting pharmaceutical start-up companies**

**Basel, January 16, 2006** The Novartis Venture Fund, a significant investor in health care companies in the Basel area as well as worldwide, begins 2006 with significantly improved liquidity and a balanced investment portfolio.

For the first time ever, the Novartis Venture Fund achieved in 2005 a positive ratio of exits – the successful divestitures of businesses that it has supported – to new investments. Since its creation in 1997, the Fund has provided support to nearly 140 new companies. It now has a balanced range of investments in firms at all stages of the start-up business cycle, from new investments through to stock market flotations or acquisitions.

The Novartis Venture Fund has firmly established itself as a leading participant in the Swiss venture capital scene, said Dr. Daniel Vasella, Chairman and CEO of Novartis. The recent strong business performance by the Fund has positioned itself more than ever to fulfill its role as a catalyst for helping young companies developing novel medicines.

The Novartis Venture Fund plays an important role in supporting start-ups in the tri-national BioValley area based around Basel. At the end of 2005, the portfolio of the Fund included investments in 62 private companies.

Among the highlights of 2005 were the initial public offerings of Speedel, Glycart and Transform Pharmaceuticals. Share holdings were also sold in Eyetech Pharmaceuticals, Idenix Pharmaceuticals and Theravance.

Thanks largely to these transactions, liquidity increased significantly, reaching approximately USD 190 million at the end of 2005. The Novartis Venture Fund is now well positioned to provide further support to its most promising portfolio companies and to make new investments.

In 2005, the Novartis Venture Fund committed a total of USD 16 million in funding. Slightly more than half went to new investments, while the remainder was used to provide further support for existing members of its portfolio.

One of our key success factors is the experienced management team, comprised of experts with the ability to evaluate qualitatively the innovativeness of a project, the solidity of the business plan and business model, as well as the managerial competencies of the entrepreneurs said Dr. François L. Eplatténier, Chairman of the Novartis Venture Fund.

With US investments increasing in both relevance and number, the Novartis Venture Fund has set up a new office in Boston that is close to the Novartis Institutes for BioMedical Research (NIBR) headquarters in Boston, which is also a key center for the US biotechnology industry.

#### **About Novartis**

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**- Investor Relations Release -**

**Novartis decides not to make offer to acquire Berna Biotech**

Basel, January 10, 2006 - After completion of due diligence and an assessment of the potential benefits and risks of an acquisition, Novartis has decided not to make an offer for Berna Biotech AG.

Novartis announced in December that it was considering whether to acquire Berna Biotech AG after Crucell N.V., a Dutch biotechnology company, made an offer earlier in December to acquire the Swiss company through an all-share exchange offer.

About Novartis

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**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: February 2, 2006

By: /s/ MALCOLM B. CHEETHAM

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