

NOVARTIS AG  
Form 6-K  
August 17, 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 dated August 16, 2006  
(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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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:

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:

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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:

Enclosures:

Novartis releases Fluvirin® influenza virus vaccine to US distributors (Basel, August 16, 2006)

Novartis and Schering-Plough announce collaboration to develop novel once-daily combination therapy for asthma and COPD (Basel, August 14, 2006)



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**- Investor Relations Release -**

**Novartis releases Fluvirin® influenza virus vaccine to US distributors**

- *Fluvirin vaccine release signals the first availability of injectable flu vaccine in the United States this year*
- *Shipments support public health efforts for early and sustained immunization planning*
- *Deliveries to continue throughout vaccination period until the end of the year*

**Basel, August 16, 2006** - Novartis announced today the delivery and release of its first shipments of Fluvirin® influenza virus vaccine to the United States for the 2006-2007 influenza season, with continued shipments expected to follow through the end of the year.

Ensuring a reliable and safe supply of Fluvirin for the United States is a top priority for Novartis Vaccines, and it is very rewarding to have been able to provide products early in the vaccination season to help jump-start immunizations. We plan to maintain a continuous supply during the vaccination season, said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics.

A dependable flu vaccine supply is critical for public health authorities to increase vaccination rates aimed at protecting more people from the threat of seasonal influenza. We intend to continue providing leadership and innovation in influenza vaccines through both our traditional flu vaccine operations as well as flu cell culture vaccines in development, Reinhardt said.

The US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) released in early August the first lots of Fluvirin vaccine, positioning it to become the first trivalent inactivated influenza vaccine (TIV), or flu shot, available this year. The lots delivered and released to distributors this week correspond to more than one million doses of Fluvirin vaccine.

Novartis Vaccines intends to deliver the majority of its Fluvirin vaccine production by the end of October, with additional shipments expected through the end of 2006.

The recently expanded vaccination recommendations highlight the importance of getting vaccinated prior to - and even at the onset - of the flu season to help reduce transmission of influenza to those who are most vulnerable, said John Vavricka, head of North America for Novartis Vaccines.

Annual immunization against the flu is the best way to protect individuals, their families and those with whom they have contact from influenza and to reduce the toll in mortality, suffering, and lost productivity. We are hopeful that a robust vaccine supply this season will lead to improved

vaccination rates, particularly for caregivers of young children as well as healthcare providers and those who come in contact with people in high-risk groups, Vavricka said.

Influenza vaccination is the most effective way to prevent influenza. Although the flu season can begin earlier, it usually starts in December, peaks in January or February, and continues through March. According to the US Centers for Disease Control and Prevention (CDC), while October and November are traditionally the primary vaccination months, vaccination in December or later is still recommended for those who are not vaccinated earlier. Influenza vaccination not only helps to decrease the risk of influenza and its complications for the vaccine recipient but can also reduce the risk of the virus spreading to those who come in contact with vaccinated people.

The Advisory Committee on Immunization Practices (ACIP), an advisory body of the CDC's National Immunization Program (NIP), issued updated recommendations for influenza vaccination in July 2006 calling for vaccination of the following groups:

People at high risk for influenza-related complications and severe disease, including:

- Children age 6-59 months
- Pregnant women
- People age 50 years or older
- People of any age with certain chronic medical conditions

People who live with or care for people in the high-risk groups listed above, including:

- People in households who have frequent contact with people at high risk and who can transmit influenza to these people
- Healthcare workers

Fluvirin vaccine is not indicated for children younger than age 4.

In an average year in the United States, influenza causes more than 200,000 hospitalizations and kills approximately 36,000 people, primarily in the over-65 population. Together, influenza and pneumonia are the seventh leading cause of death in the country, killing more people than any other infectious diseases. The annual direct medical costs of influenza are estimated at USD 3 billion to USD 5 billion. Total direct and indirect costs, including lost work days, of a severe flu epidemic could be as high as USD 12 billion to USD 14 billion.

#### **Update on European influenza vaccine supply**

According to the recent announcement by the European Vaccines Manufacturers (EVM), production of influenza vaccines for the 2006-2007 will be delayed due to low yields associated with the new H3N2 strains provided by the World Health Organization (WHO). The delays have affected the manufacturing campaigns for all European influenza vaccine producers. Deliveries in Europe are expected to begin in September and October, with the bulk of vaccines expected to become available later in the traditional vaccination season.

#### **About influenza and influenza vaccines**

Influenza, a contagious disease caused by the influenza virus, affects the respiratory tract, often resulting in cough, sore throat, runny or stuffy nose, as well as fever (usually high), headache, extreme tiredness, and muscle aches. It can also lead to complications such as bacterial pneumonia, dehydration and worsening of chronic medical conditions, such as congestive heart failure, asthma or diabetes. Children may get sinus problems and ear infections.

Influenza vaccination usually provides protection from influenza within about two weeks of administration. An annual vaccine closely matched to the circulating strains of influenza protects about 70% to 90% of healthy adults who are vaccinated from contracting influenza. Vaccinated people who do contract influenza generally develop milder cases than those who have not received the vaccine. Among elderly nursing home residents, the flu shot can help prevent cases and deaths from the flu.



Influenza vaccines are updated each year to address changes in the viruses. Traditional flu shots are made from viruses that have been inactivated (killed), while the nasally delivered vaccine is made with live attenuated influenza viruses. The influenza vaccine for the 2006-2007 season contains the A/New Caledonia/20/99 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like and B/Malaysia/2506/2004-like influenza virus antigens.

Several influenza vaccines are available in the US. Each vaccine has its own specific indications, contraindications and side effects. Before vaccination, people should consult their healthcare providers to determine if they have any conditions precluding them from receiving a vaccine.

#### **Important safety information for Fluvirin influenza virus vaccine**

The most common side effect of vaccination with Fluvirin vaccine is soreness at the injection site. Less common side effects include fever, malaise, myalgia and allergic reactions. Fluvirin vaccine should not be administered to anyone with a history of hypersensitivity to any component of the vaccine, including eggs, egg products or thimerosal. As is the case with most drugs and vaccines, there is a chance that a serious allergic reaction, serious illness or even death could occur as a result of vaccination with Fluvirin vaccine. Generally, persons should not be vaccinated during an acute febrile illness. Vaccination should be delayed in persons with an active, unstable neurological disorder, but should be considered when the disorder has been stabilized. The occurrence of any neurological symptoms or signs following administration of any vaccine is a contraindication to further use. Fluvirin vaccine is not indicated for use in children under four years of age. Persons should consult with their healthcare providers if they are pregnant and/or are taking other medications. Fluvirin vaccine may not protect 100% of individuals who are susceptible to influenza. Before administering Fluvirin vaccine, please see full prescribing information.

#### **Disclaimer**

This release contains certain forward-looking statements, relating to the Novartis Group's business, which can be identified by the use of forward-looking terminology such as "expected", "plan to", "aimed at", "intend to", "we are hopeful" or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of the Fluvirin influenza virus vaccine or other candidate vaccines. Such statements reflect current views with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that vaccine candidates will be approved for any indications in any market or that Fluvirin vaccine or any candidate vaccines will reach any particular sales levels. In particular, management's expectations regarding commercialization of Fluvirin or other vaccine candidates could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability of Novartis to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Novartis AG's current Form 20-F on file with the U.S. 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 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 Vaccines & Diagnostics is a new division of Novartis focused on the development of preventive treatments and tools and was formed following the recent acquisition of Chiron Corporation. The division has two businesses: Novartis Vaccines and Chiron. Novartis Vaccines is the world's fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the US. Leading products also include meningococcal, pediatric and travel vaccines. Chiron, the

blood testing and molecular diagnostics business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world's blood supply.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group's businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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#### Media materials

For images and video related to Fluvirin influenza virus vaccine, please visit [www.thenewsmarket.com/novartisvaccines](http://www.thenewsmarket.com/novartisvaccines). Journalists may register and download print-quality images and broadcast-standard video from this site at no charge.

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**- Investor Relations Release -**

**Novartis and Schering-Plough announce collaboration to develop novel once-daily combination therapy for asthma and COPD**

- *New inhaled therapy will combine the bronchodilator indacaterol (QAB149) of Novartis with Schering-Plough's inhaled corticosteroid mometasone*
- *Novel once-daily combination has the potential to help patients by improving on efficacy, convenience and compliance of current medications*
- *Asthma estimated to cause more than 180,000 deaths worldwide annually[1], while chronic obstructive pulmonary disease (COPD) affects one in 15 smokers[2]*
- *Agreement marks latest collaboration between the two companies and further strengthens Novartis respiratory portfolio*

**Basel, August 14, 2006** - Novartis has entered into a global collaboration with Schering-Plough Corporation to develop and commercialize a novel once-daily inhaled fixed-dose combination therapy for the treatment of asthma and chronic obstructive pulmonary disease (COPD), two of the world's most prevalent and urgent respiratory diseases.

The goal is to develop a new therapy that would combine the therapeutic benefits of the once daily long and fast acting Beta2-agonist QAB149 (indacaterol) of Novartis and Schering-Plough's once-daily oral corticosteroid mometasone (Asmanex®) in a single inhalation device. The combined product would have the potential to offer patients improved symptom control, convenience and compliance through once-daily dosing.

Combination products containing inhaled corticosteroids and long-acting Beta2-agonists are the largest class within the growing worldwide asthma and COPD market. An inhaled bronchodilator-corticosteroid combination with true 24-hour efficacy and rapid onset of action could be an important new treatment option to help patients suffering from these serious and life-threatening diseases that continue to claim millions of lives annually.

By working together, we can combine our expertise and commitment in the respiratory field to provide improved treatment options that will potentially benefit millions of patients with asthma and COPD. The combination of indacaterol with mometasone would be a significant addition to our respiratory pipeline, demonstrating our commitment to the development of important new products to improve disease control for patients," said Thomas Ebeling CEO of Novartis Pharma AG.

James Shannon, MD, Global Head of Development at Novartis Pharma AG, added: "To maximize patient benefits from a novel respiratory medication such as indacaterol, it is essential to consider both flexibility and the optimum inhaler device options for the product. Novartis is planning to





develop indacaterol both as a monotherapy and in fixed-dose combinations to provide flexible therapeutic options for physicians and patients.

The indacaterol-mometasone development is the latest stage in a long-term collaboration between Novartis and Schering-Plough. In November 2002, the two companies announced an agreement granting Schering-Plough exclusive US distribution and marketing rights to the Foradil® Aerolizer® (formoterol fumarate inhalation powder). In April 2003, the companies announced an agreement to jointly develop and market worldwide a novel therapy combining Foradil® (formoterol fumarate) with Schering Plough's Asmanex®.

Novartis and Schering-Plough will share the costs of developing the indacaterol-mometasone combination product. No initial payments will be made by either party.

### **Novartis commitment to respiratory diseases**

Novartis is committed to the research and development of novel compounds to help patients worldwide with various respiratory diseases. This latest agreement with Schering-Plough further strengthens the Novartis respiratory portfolio, which already contains a number of marketed drugs such as Xolair®, Foradil® for asthma and TOBI® for cystic fibrosis as well as late-stage pipeline products such as QAB149 and early-stage compounds for the treatment of diseases such as asthma and COPD.

### **About asthma and COPD**

Asthma is a chronic inflammatory lung disease that affects more than 300 million people worldwide[3], of whom an estimated 15 million suffer from severe disease[4]. The health and quality of daily life for these patients are often severely affected, with more than 180,000 people believed to die from asthma each year throughout the world[1].

COPD (chronic obstructive pulmonary disease) is the world's fourth leading cause of death. It is an irreversible and chronic obstruction of the airways caused primarily by smoking. About four percent of the population in the US, Europe and Japan are estimated to have the disease, which is estimated to affect at least one in 15 people who smoke tobacco products. Symptoms, which are similar to those found in chronic bronchitis and emphysema, progress slowly and eventually lead to a largely irreversible loss of lung function. COPD is expected to become the third leading cause of death by 2020, while COPD death rates are estimated to be very low for people under age 45, complications and deaths increase steeply with age[2].

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4. American Thoracic Society. Proceedings of the ATS workshop on refractory asthma. Current understanding, recommendations, and unanswered questions. *Am J Respir Crit Care Med* 2000; 162:2341-2351

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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: August 16, 2006

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial  
Reporting and Accounting