

NOVARTIS AG  
Form 6-K  
April 30, 2007

# 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 April 27, 2007

(Commission File No. 1-15024)

## Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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

Form 20-F:  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:



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- Investor Relations Release -

**Optaflu®, the Novartis cell culture-derived influenza vaccine, receives positive opinion supporting European Union regulatory approval**

- *Novartis leading the introduction of influenza cell culture manufacturing – the first major innovation in influenza vaccine manufacturing in more than 50 years*
- *Optaflu® to help meet growing need for seasonal influenza vaccines, production technology has potential for quick scale-up in case of an influenza pandemic*
- *Novartis proprietary cell culture technology offers possibility to obtain a better matched vaccine with circulating viruses than currently available technology*

**Basel, April 27, 2007** Novartis has received a positive opinion supporting European Union approval of its cell culture-derived seasonal influenza vaccine Optaflu®, which is aiming to become the first influenza vaccine to utilize a mammalian cell line, rather than chicken eggs, for antigen production.

The Committee for Medicinal Products for Human Use (CHMP), which reviews applications for all 27 countries in the EU as well as Iceland and Norway, has recommended approval of this new vaccine. The European Commission generally follows the recommendations of the CHMP and delivers its final decision within two to three months.

Novartis Vaccines is pleased with this positive recommendation for Optaflu, the first cell culture-derived influenza vaccine and the first major innovation in influenza vaccine manufacturing in more than 50 years, said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics. Optaflu contributes to meeting the growing demand for seasonal influenza vaccines, and this production technology offers the potential for quick scale-up of manufacturing in the event of an influenza pandemic.

A submission is anticipated in 2008 for US regulatory approval of this cell culture-derived seasonal influenza vaccine.

More than 3,400 people received Optaflu during the clinical development program evaluating the vaccine's safety and immunogenicity. Data reviewed by CHMP from the clinical program showed Optaflu fulfilled all of the Committee's immunogenicity criteria.

The data further showed the cell culture-derived influenza vaccine was comparable to conventional egg-based vaccines in efficacy and tolerability. Additives, such as antibiotics, are avoided in the Optaflu production process. Additionally, people allergic to eggs and egg products can benefit from receiving this vaccine since it is created without egg proteins.

Like established conventional egg-based vaccines, Optaflu is administered via intramuscular injection. Data from the Phase III clinical program were presented at the Influenza Vaccines for the World Congress (IVW) meeting in October 2006.

#### **About cell culture technology and the Novartis proprietary cell line**

Cell culture manufacturing is the first major innovation in influenza vaccine manufacturing in more than 50 years. It represents a new approach to vaccine production whereby influenza virus is propagated in readily available mammalian cell lines rather than in chicken eggs.

Virus cultivation utilizing the Novartis proprietary cell line as an exclusive host offers the possibility of more robust virus proliferation since most circulating viral strains are unable to replicate in chicken eggs. In a next generation of products, it also offers the possibility for vaccine seed strain development that more closely matches the original wild virus because cell culture technology eliminates the need for passage through eggs where the virus may be forced to adapt in order to replicate. As a result, the antigen included in the vaccine may express more authentically the surface of the wild type virus, potentially translating into a better immunogenic and effective response.

The Novartis proprietary cell culture technology enables flexible, faster start-up of vaccine manufacturing. With the advent of this technology, Novartis Vaccines is contributing to meet the growing need for seasonal influenza vaccines and quickly respond to a potential pandemic influenza threat.

#### **About influenza and pandemic influenza**

Influenza can cause mild to severe illness and at times can lead to death. Worldwide, influenza epidemics result in approximately 250,000 to 500,000 deaths each year<sup>(1)</sup>. Influenza-related complications can include pneumonia and dehydration, and worsening of chronic conditions, such as congestive heart failure, asthma, or diabetes<sup>(2)</sup>. The World Health Organization (WHO) and its Global Influenza Surveillance Network recommend vaccination as the principal method for preventing influenza<sup>(1)</sup>.

Increased circulation of avian influenza A/H5N1 virus has been documented in Asia and Europe. On a pandemic threat scale of one to six, the World Health Organization currently ranks the H5N1 risk at phase three. This virus is highly contagious in chickens, adding the possibility that a pandemic strain could emerge at a time when egg supplies are lower than usual due to a previous epidemic in chickens. Novartis proprietary cell culture line offers an alternative to traditional egg-derived vaccines.

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#### **References**

1. World Health Organization Influenza Fact Sheet  
<http://www.who.int/mediacentre/factsheets/fs211/en/index.html> Accessed October 10, 2006
2. Centers for Disease Control and Prevention (CDC) Questions & Answers: The Disease  
<http://www.cdc.gov/flu/about/qa/disease.htm> Accessed October 10, 2006

#### **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 to help, potential, possibility, aiming to, recommended, generally follows the recommendations, anticipated, potentially, can, could, or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Optaflu. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Optaflu to be materially different



from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Optaflu will be approved for any indications in any market or that Optaflu will reach any particular sales levels. In particular, management's expectations regarding Optaflu could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; competition in general; the ability of Novartis to obtain or maintain patent or other proprietary intellectual property protection; 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 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 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 and Diagnostics is a division of Novartis focused on the development of preventive treatments and tools. Novartis Vaccines is the world's fifth-largest manufacturer and second-largest supplier of influenza vaccines in the US. The division's 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. For more information, please visit <http://www.novartisvaccines.com>.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates 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 the Novartis Vaccines influenza products, 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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**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: April 27, 2007

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting

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