NOVARTIS AG Form 6-K June 13, 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 June 13, 2007 (Commission File No. 1-15024)

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(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:** x Form 40-F: o

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: o No: x

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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: o No: x

**Novartis International AG** 

Novartis Global Communications CH-4002 Basel Switzerland http://www.novartis.com

- Investor Relations Release -

#### Novartis gains European approval for its innovative flu vaccine Optaflu®

- Novartis proprietary cell culture technology offers independence from chicken eggs for vaccine production and enables flexible, faster start-up of manufacturing
- New technology provides possibility to obtain a better matched vaccine with circulating viruses than currently available technologies

Basel, June 13, 2007 Optaflu®, the first influenza vaccine to utilize a Novartis proprietary cell line for the production of viral antigen components rather than the traditional chicken eggs, has received European Union approval in all 27 member states, as well as Iceland and Norway.

Optaflu, has been approved for use in vaccination against seasonal influenza and contributes to meeting the growing demand for seasonal influenza vaccines. The use of a Novartis proprietary cell culture technology enables a faster and more flexible start-up of vaccine manufacturing, offering the potential to more quickly respond to a potential pandemic influenza threat.

Optaflu marks the first major innovation in influenza vaccine manufacturing in over 50 years. This vaccine, which is based on our proprietary cell culture technology, would provide for a more flexible and reliable production process, so as to contribute to meeting the ongoing need for seasonal influenza vaccines and the potential need for influenza vaccines in the event of a pandemic, said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics.

This new vaccine is expected to be available in Germany and Austria for the 2007/2008 influenza season and to be available in the remaining EU countries for the 2008/2009 influenza season. A submission for US regulatory approval is anticipated for 2008.

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

Increased circulation of avian influenza A/H5N1 virus has been documented in Asia and Europe. On a pandemic threat scale of one to six, WHO 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.

More than 3,400 people received Optaflu during the clinical development program evaluating the vaccine s safety and immunogenicity. This data showed Optaflu fulfilled all of the European Union s immunogenicity and safety criteria.

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

Optaflu is administered via intramuscular injection like established, conventional egg-based vaccines. Data from the Phase III clinical program were presented at the Influenza Vaccines for the World Congress (IVW) meeting in October 2006. Additional data was also presented at Options for the Control of Influenza VI Conference (Options VI) in Toronto in June 2007.

#### Cell culture technology first new innovation for influenza vaccines in 50 years

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. As 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 potential pandemic influenza threats.

#### 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 potential, possibility, recommended, anticipated, potentially, can, expected or expressions, or by express or implied discussions regarding potential marketing approvals, commercialization or indications 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 and/or Novartis proprietary cell culture technology 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. The division is comprised of two activities: Novartis Vaccines and Chiron. Novartis Vaccines is the world s fifth-largest manufacturer and second-largest supplier of influenza vaccines in the US. The division s products include influenza, 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. 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.

#### References

(1) WHO Cumulative Number of Confirmed Human Cases of Avian Influenza, WHO Web site http://www.who.int/csr/disease/avian\_influenza/country/cases\_table\_2006\_10\_31/en/index.html, accessed May 31, 2007

(2) WHO Strategic Action Plan for Pandemic Influenza 2006-2007, WHO website http://www.who.int/csr/resources/publications/influenza/WHO\_CDS\_EPR\_GIP\_2006\_2c.pdf, accessed May 31, 2007

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#### **Novartis Media Relations**

#### **Corinne Hoff**

Novartis Global Media Relations

+41-61-324-9577 (direct)

+41-79-248-5717 (mobile)

corinne.hoff@novartis.com

## **Eric Althoff**

Novartis Vaccines and Diagnostics Communications

+1-510-923-6500

+1-510-387-7604(US mobile)

eric.althoff@novartis.com

e-mail: media.relations@novartis.com or nvd.communications@novartis.com

### **Novartis Investor Relations**

#### International

Ruth Metzler-Arnold	+41 61 324 7944
Katharina Ambühl	+41 61 324 5316
Nafida Bendali	+41 61 324 3514
Jason Hannon	+41 61 324 2152
Thomas Hungerbuehler	+41 61 324 8425
Richard Jarvis	+41 61 324 4353

# North America

Ronen Tamir	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

### **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: June 13, 2007 By: /s/ MALCOLM B. CHEETHAM

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