

NOVARTIS AG
Form 6-K
October 20, 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 October 19, 2006

(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: 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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Yes: o **No: x**

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**

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- Investor Relations Release -

Pivotal Phase III trial results show Novartis cell culture-derived influenza vaccine well tolerated and efficacious

- *New Phase III data show effective immune response and good tolerability of cell culture-derived influenza vaccine compared to traditional egg-derived vaccine*
- *New vaccine manufacturing technology uses mammalian cell culture as an alternative host to more than 50-year-old chicken egg process for virus replication*

Basel, October 19, 2006 Novartis announced today results of pivotal Phase III clinical trial data for its innovative cell culture-derived influenza vaccine demonstrating that it is highly capable of producing an immune response (immunogenic), one at least as strong as the traditional egg-derived influenza vaccine Aggripal® for each of the three influenza strains studied.

The findings, which were presented at the Second International Conference on Influenza Vaccines for the World (IVW 2006), also showed the cell culture-derived influenza vaccine was well tolerated and no difference in the safety profile was observed compared to traditional egg-based vaccines.

Novartis is committed to bring cell culture-derived influenza vaccine to market, said Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostic. These data support this effort and help to further establish Novartis as a leader in bringing this innovative vaccine technology to the next level.

Cell-culture based influenza vaccines promise many advantages over egg-based production, including greater reliability and reduced production lead time that could be critical in a pandemic. Novartis submitted its cell culture-derived influenza vaccine for European Union approval in June 2006, while US clinical studies began in 2005 and are ongoing.

This cell culture-derived influenza vaccine technology utilizes an alternative approach to vaccine production by which influenza virus is grown in readily available mammalian cell lines (Madin-Darby Canine Kidney, or MDCK cells). Conventional influenza vaccine production utilizes chicken eggs as hosts for virus replication followed by virus purification.

About the study results

A large-scale Phase III study was conducted in Poland during the 2004-2005 influenza season. In this observer-blind, multi-center program, 1,300 adults (age 18-60) and 1,354 elderly (age 60 or older) were randomized to receive the new Novartis cell culture-derived influenza vaccine or an egg-derived, conventional vaccine (Agrippal). Each subject received a single 0.5 ml intramuscular injection. The ability for the vaccine to provoke an immune response (immunogenicity) against the influenza viruses was evaluated according to the European Union's Committee for Medicinal Products Human Use (CHMP) criteria.

The cell culture vaccine met all three of the CHMP full criteria, and showed no difference between the cell culture-derived influenza vaccine and the conventional egg-based vaccine. The incidences of local and systemic adverse events were similar between the two vaccines in both adult and elderly subjects, indicating that the cell culture-derived vaccine was as well tolerated as the egg-derived vaccine.

About influenza

Influenza is a contagious, potentially serious respiratory illness caused by influenza viruses that attack the upper respiratory tract. It can cause mild to severe illness, and at times can lead to death. Influenza viruses easily spread from person to person in respiratory droplets created by coughing and sneezing. Although difficult to assess, annual influenza epidemics are thought to result in between three and five million cases of severe illness and between 250,000 and 500,000 deaths annually around the world.

Disclaimer

This release contains certain forward-looking statements, relating to Novartis Group's business, which can be identified by the use of forward-looking terminology such as "is committed to," "promise," or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of 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 they will reach any particular sales levels or that Novartis' cell culture-derived influenza vaccine will receive European Union approval. In particular, management's expectations regarding commercialization of cell culture-derived influenza vaccines and particular 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 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 and 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. Novartis Vaccines and Diagnostics' 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 99,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Media materials

For images and video related to Novartis' cell culture-derived influenza vaccine development, please visit 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: October 19, 2006

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial
Reporting and Accounting