NOVARTIS AG
Form 6-K
September 27, 2010

# 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 September 24, 2010**

**(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:

**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):

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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

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**- Investor Relations Release -**

**Novartis obtains CHMP positive opinion for its investigational pre-pandemic influenza vaccine Aflunov® to help protect against (H5N1) avian influenza**

- *Aflunov contains the MF59 adjuvant which has been shown to generate long lasting immune memory against H5N1 variants*(1), (2), (3)

- *Prior to pandemic outbreak, Aflunov may offer an important means to induce priming of healthcare and emergency workers and those at risk of H5N1 exposure*

- *Over 500 human cases of H5N1 have been reported in Asia, Africa, the Pacific and Europe by WHO, with an overall mortality rate of approximately 60 percent*(4), (5)

**Basel, September 24, 2010** Novartis announced today that the European Medicines Agency s Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Aflunov®, an investigational pre-pandemic avian influenza vaccine. The CHMP is endorsing the approval of Aflunov for active immunization against H5N1 subtype of Influenza A virus in adults 18 years of age and older. H5N1 (commonly referred to as avian or bird flu) accounts for most avian influenza outbreaks globally and is a serious health concern given its potential to evolve into a deadly pandemic strain at any time(6).

The CHMP recommendation serves as the basis for a European Commission licensing Decision. Based on the CHMP recommendation, a marketing authorization for Aflunov could be granted in all the European Union and EEA countries. The marketing authorization is expected to be granted before year-end.

Upon approval, we expect Aflunov to be an important addition to our portfolio of pandemic preparedness solutions, said Andrin Oswald, Head of Novartis Vaccines and Diagnostics Division. The onset of a pandemic can be very rapid, leaving little or no time to prepare. Vaccinating in advance may prevent the potential devastation of a pandemic outbreak.

H5N1 is presently the virus of greatest concern among all avian influenza viruses(7). H5N1 is currently circulating in birds, poultry and many other animal species around the world and has already infected humans that have been in contact with infected animals(7), (8). While human infections are continuing to rise, ability of the virus to spread from human to human has not been demonstrated yet(7). To date, there have been more than 500 cases of serious illness and more than 300 deaths(5). H5N1 morbidity and mortality rates remain significantly higher than those

associated with seasonal influenza and any recent pandemic(4), (9), (10). According to the World Health Organization (WHO), H5N1 has met all prerequisites for starting a pandemic except for the ability to spread efficiently and sustainably among humans(7).

Vaccines are considered the first line of defense against pandemic influenza(11). Transmission of influenza virus during a pandemic can be rapid, leaving little or no time to prepare. Thus, proactive pre-pandemic vaccination to prime populations at risk or vaccine stockpiling may be a more

adequate way to help protect those at risk of H5N1 infection(12), those who would form the first line of response during a potential pandemic, such as healthcare and emergency workers, and those critical to maintaining business and economic continuity.

In clinical trials, two doses of Aflunov demonstrated antibody titers considered protective in more than 85% of vaccinated individuals (homologous seroprotection rate)(13). Aflunov was also shown to elicit cross-reactive antibodies against many of the H5 strains that have caused human disease(14). Additionally, a single vaccination with Aflunov (H5N1, A/Vietnam/1194/2004) induced high and rapid serological response in subjects primed 6-8 years previously with two doses of a different surrogate H5 vaccine, having same formulation and including the same MF59 adjuvant as Aflunov but using the strain H5N3.

The EU regulatory filing for Aflunov will form the basis for further filings in other parts of the world including Asia, where H5N1 has been reported in many countries(7).

**About Aflunov**

Aflunov is an investigational influenza vaccine for the active immunization against H5N1 subtype of Influenza A virus. H5N1 is commonly referred as avian or bird flu. Aflunov contains the MF59 adjuvant and is intended for use before or upon declaration of a H5N1 avian influenza pandemic. In clinical trials Aflunov has demonstrated a broad and durable immune response(1), (2), (3), with tolerability comparable to seasonal adjuvanted vaccines(15). It can be stockpiled for future use with sufficient shelf life.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as may, endorsing, potential, expect, potentially, recommendation, can, expected, will, could or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Aflunov or regarding potential future revenues from Aflunov. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Aflunov to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aflunov will be approved for sale in any additional market. Nor can there be any guarantee that Aflunov will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Aflunov could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected world flu or other disease patterns; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in 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. The division has two businesses: Novartis Vaccines and Novartis Diagnostics. Novartis Vaccines is the world s fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the US. The division s products also include meningococcal,

pediatric and travel vaccines. Novartis Diagnostics, the blood testing 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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For Novartis multimedia content, please visit www.thenewsmarket.com/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**

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| Date: September 24, 2010 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |