

NOVARTIS AG  
Form 6-K  
August 07, 2009

## **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 5, 2009**

**(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:

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**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:

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**- Investor Relations Release -**

**Novartis begins shipment of Fluvirin® seasonal influenza vaccine for the U.S. market ahead of schedule**

- *Novartis Vaccines ships doses of seasonal influenza vaccine to the U.S. market aided by an expedited FDA review*
- *Providing 30 million doses of Fluvirin vaccine in the U.S., to support the annual seasonal influenza vaccination campaign*
- *Early delivery of vaccine will allow public health officials to begin the vaccination campaign weeks ahead of the normal schedule*

**Basel, August 5, 2009** Novartis Vaccines has started shipping seasonal influenza vaccine to U.S. healthcare facilities for the 2009-2010 season. The company delivered Fluvirin® influenza virus vaccine, which has been approved by the U.S. Food and Drug Administration (FDA), to the U.S. weeks ahead of schedule in anticipation of the increased demand for seasonal influenza vaccine created by the current global (A) H1N1 influenza pandemic.

With the (A) H1N1 influenza pandemic underway, it is important that we take every possible precaution to help protect U.S. citizens from all circulating strains of influenza, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. By receiving the seasonal influenza vaccine early, physicians and public health officials can better prepare for the upcoming flu season.

An estimated 36,000 people in the United States die each year from the flu and another 200,000 are hospitalized(1). Early arrival of the seasonal influenza vaccine will also allow public health officials to begin administering vaccinations weeks ahead of their normal schedule, which is in accordance with guidelines from the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC)(2). Federal health officials advise that the single best way to protect against the flu is to get vaccinated each year, and that in general anyone who wants to reduce their chances of getting the flu can get vaccinated(3).

Novartis Vaccines will provide the U.S. market with approximately 30 million doses of Fluvirin vaccine, indicated for patients 4 years and older. Fluvirin vaccine contains antigens to the three influenza virus strains for this year's vaccine recommended by the World Health Organization (WHO):

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- A/Brisbane/59/2007, IVR-148 (H1N1)
- A/Uruguay/716/2007, NYMC X-175C (H3N2) (an A/Brisbane/10/2007-like virus)
- B/Brisbane/60/2008(4)

Novartis Vaccines committed early on that we would not let production of a pandemic vaccine get in the way of our ongoing commitment to provide seasonal influenza vaccine for the U.S. market, Oswald said. We have been able to meet that promise with the early delivery of Fluvirin to the

U.S. Our next goal will be to bring an (A) H1N1 influenza vaccine for public health use as soon as possible.

### **About seasonal influenza**

Seasonal influenza is a highly communicable, acute viral infection that predominantly attacks the respiratory tract and sometimes the lungs. It can cause mild to severe illness and can lead to death(5).

The number of people in the U.S. who die every year from the flu is similar to the more than 40,000 people in the U.S. estimated to die from breast cancer every year(6) and about half of the estimated 70,000 people who die annually of diabetes and its complications(7). During the 2007-2008 seasonal influenza season, 83 children were reported to have died of influenza-related causes(8). Of the 63 whose vaccination status was known, 58 (92 percent) were not vaccinated according to recommendations(9). Final numbers for the 2008-2009 flu season are not yet available.

Influenza vaccination is one of the most effective public health interventions ever implemented, sparing millions of people from complications of the infectious disease. Use of currently available seasonal flu vaccines has been calculated to save more than 8 million lives annually, translating to one person saved every five seconds(10).

ACIP recommends seasonal influenza vaccinations as the principal method of preventing seasonal influenza. The vaccine is recommended for those at greatest risk for serious complications, including:

- Children between 6 months and 18 years of age
- Pregnant women
- People 50 years of age and older
- People of any age with certain chronic health conditions, such as asthma, diabetes or heart disease
- People in nursing homes and other long-term care facilities,
- Household contacts of person at high risk for complications from influenza,
- Household contacts and out-of-home caregivers of children less than 6 months of age
- Healthcare workers(11)

### **Important safety information**

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. The most common side effect of vaccination with Fluvirin influenza virus 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. Generally, persons should

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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**

The foregoing release contains forward-looking statements that can be identified by terminology such as will, can, committed, would, commitment, goal, recommends, recommended, or similar expressions, or by express or implied discussions regarding Novartis' potential production output for Fluvirin and A(H1N1) vaccines, and regarding potential future revenues from

Fluvirin vaccine. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis will achieve any particular production output for its Fluvirin or A(H1N1) vaccines, or indeed that the A(H1N1) vaccine will be approved for sale in any market. Nor can there be any guarantee that Fluvirin vaccine will achieve any particular levels of revenue in the future. In particular, management's expectations 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 manufacturing difficulties or delays; 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 Chiron. 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. 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 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 each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 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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**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 5, 2009

By: /s/ MALCOLM B. CHEETHAM

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