

NOVARTIS AG  
Form 6-K  
October 06, 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 October 6, 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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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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**Novartis International AG**  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis completes shipment of US supply of Fluvirin® seasonal influenza vaccine**

- *27 million doses shipped to US market by Novartis providing more seasonal flu vaccine earlier than in any previous year*
- *Shipments completed ahead of normal seasonal vaccine delivery schedules to allow for earlier vaccination*
- *First shipments of A(H1N1) vaccine delivered to US government less than four months after the pandemic declaration by the WHO*

**Basel, October 6, 2009** Novartis announced today that the company has completed its entire shipment of seasonal influenza vaccine to the United States for the 2009/2010 season. As previously anticipated, the company delivered 27 million doses of Fluvirin® influenza virus vaccine, which has been approved by the U.S. Food and Drug Administration (FDA). Novartis completed this season's shipment earlier than in previous years, in anticipation of demand for earlier vaccination with seasonal influenza vaccine created by the current global A(H1N1) influenza pandemic.

Novartis is pleased to have delivered more seasonal influenza vaccine to the US market by the end of September than we have in any previous year allowing more people to get their vaccine early in the season, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. We are relieved to have been able to complete our deliveries ahead of schedule despite the challenging task to produce large quantities of A(H1N1) pandemic vaccines at the same time. We hope that the early delivery of our Fluvirin vaccine will help physicians and public health officials better prepare for the upcoming flu season and balance the needs for pandemic and seasonal vaccination.

On September 27, Novartis also began shipments of the first doses of its influenza A(H1N1) 2009 monovalent vaccine(1) to the United States. The early shipment is the first of an accelerated effort to provide as much A(H1N1) vaccine as soon as possible, despite the low yield seen with the initial production seed strain provided by the World Health Organization. Production has switched to a new higher yielding seed strain which will allow deliveries of higher volumes later in the year.

Novartis Influenza A(H1N1) 2009 monovalent vaccine was approved by the FDA on September 15, 2009. The A(H1N1) vaccine is an inactivated subunit vaccine approved for active immunization of persons 4 years of age and older, including patients with underlying chronic medical conditions. The US Department of Health and Human Services (HHS) awarded Novartis two contracts totaling USD 979 million for purchase of H1N1 bulk vaccine and the Novartis proprietary MF59 adjuvant.



The Novartis seasonal influenza vaccine, Fluvirin is 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) in January 2009:

- 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(2)

#### **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(3).

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(4) and about half of the estimated 70,000 people who die annually of diabetes and its complications(5). During the 2007-2008 influenza season, 83 children were reported to have died of influenza-related causes(6). Of the 63 whose vaccination status was known, 58 (92 percent) were not vaccinated according to recommendations(7). 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(8).

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(9)

**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 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.

### **Important Safety Information for US Market**

Adverse reaction information is based on studies conducted with seasonal trivalent Influenza Virus Vaccine manufactured by Novartis (Fluvirin). The most frequently reported adverse reactions are mild hypersensitivity reactions (such as rash), local reactions at the injection site, and influenza-like symptoms. For patients who have experienced Guillain-Barré syndrome within 6 weeks of receipt of prior influenza vaccine, the decision to administer Influenza A (H1N1) 2009 Monovalent Vaccine should be based on careful consideration of the potential benefits and risks. Immunocompromised persons may have a reduced immune response to Influenza A (H1N1) 2009 monovalent vaccine.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "hope," "will," or similar expressions, or by express or implied discussions potential future deliveries of influenza vaccines, or regarding potential future revenues from influenza vaccines. 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 successfully meet its delivery obligations for its influenza vaccines. Neither can there be any guarantee that Novartis' influenza vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Novartis' influenza vaccines could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing difficulties or delays, including unexpected difficulties with our flu cell culture manufacturing facility and processes; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 prevents the spread of infections through the development and marketing of innovative technologies that enable early detection of pathogens to protect the world's blood supply and prevent the spread of infectious diseases.

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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**Footnotes**

(1) This project has been funded in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number HHSO100200800072I.

(2) World Health Organization, Recommended composition of influenza virus vaccines for use in the 2009-2010 northern hemisphere influenza season, available at [http://www.who.int/csr/disease/influenza/recommendations2009\\_10north/en/index.html](http://www.who.int/csr/disease/influenza/recommendations2009_10north/en/index.html), accessed on July 20, 2009

(3) Novartis Vaccines & Diagnostics, Inc., Seasonal Influenza Fact Sheet, available at <http://www.novartis.com/downloads/newsroom/seasonal-flu-fact-sheet.pdf> accessed on July 20, 2009

(4) The Centers for Disease Control and Prevention, Breast Cancer Statistics, available at [www.cdc.gov/cancer/breast/statistics](http://www.cdc.gov/cancer/breast/statistics), accessed on July 20, 2009

(5) The Centers for Disease Control and Prevention, National Diabetes Fact Sheet, United States 2005, available at [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2005.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf) accessed on July 20, 2009

(6) The Centers for Disease Control and Prevention, Questions and Answers: 2007-2008 Influenza (Flu) Season, available at <http://www.cdc.gov/flu/about/qa/season.htm>, accessed on July 20, 2009

(7) The Centers for Disease Control and Prevention, Influenza Activity-United States and Worldwide, 2007-08 Season, Morbidity and Mortality Weekly Report, June 27, 2008

(8) Novartis Vaccines & Diagnostics, Inc., Agrippal Product Monograph

(9) The Centers for Disease Control and Prevention, 2008-09 Influenza Prevention & Control Recommendations: Persons for Whom Annual Vaccination is Recommended, available at <http://www.cdc.gov/flu/professionals/acip/persons.htm>, accessed on July 20, 2009

**Novartis Media Relations**

**Central media line :** +41 61 324 2200

**Eric Althoff**

Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 593 4202 (mobile)  
[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

**Paul Newman**

Novartis Vaccines and Diagnostics  
+1 (617) 871 7931 (direct)  
+1 (617) 710 8953 (mobile)  
[paulc.newman@novartis.com](mailto:paulc.newman@novartis.com)

[nvd.communications@novartis.com](mailto:nvd.communications@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

**Novartis Investor Relations**

**Central phone:** +41 61 324 7944  
Ruth Metzler-Arnold +41 61 324 9980

**North America:**

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Pierre-Michel Bringer +41 61 324 1065  
John Gilardi +41 61 324 3018  
Thomas Hungerbuehler +41 61 324 8425  
Isabella Zinck +41 61 324 7188

Richard Jarvis +1 212 830 2433  
Jill Pozarek +1 212 830 2445  
Edwin Valeriano +1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto: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: October 6, 2009

By: /s/ MALCOLM B. CHEETHAM

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