NOVARTIS AG
Form 6-K
December 29, 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 December 21, 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:

**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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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

**Novartis International AG**
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**- Investor Relations Release -**

**All three Novartis A(H1N1) 2009 influenza vaccines prequalified by World Health Organization (WHO) for use in developing world**

- *First prequalification from WHO for multiple influenza A(H1N1) 2009 vaccines from a single company: Celtura® and Focetria®, both with the Novartis adjuvant MF59®, as well as unadjuvanted A(H1N1) vaccine from the Fluvirin® platform*

- *WHO prequalification of two MF59 adjuvanted vaccines highlights Novartis adjuvant s antigen sparing potential as means to enhance global supply of pandemic vaccines*

- *More than 80 million doses of Novartis influenza A(H1N1) vaccine shipped to 21 countries around the world*

**Basel, December 21, 2009** Novartis announced today that the World Health Organization (WHO) has granted prequalification for all three of its influenza A(H1N1) 2009 monovalent vaccines for supply to United Nations (UN) agencies: the cell culture-based and MF59® adjuvanted vaccine Celtura®, the egg-based and MF59 adjuvanted vaccine Focetria® as well as the egg-based A(H1N1) vaccine manufactured using the seasonal Fluvirin® platform. In addition to granting prequalified status for Novartis three influenza A(H1N1) 2009 vaccines, WHO has also granted prequalification for the company s trivalent seasonal Fluvirin® vaccine.

WHO prequalification facilitates purchasing through UN agencies and thus enhances access for developing world countries to Novartis A(H1N1) 2009 vaccines that meet unified standards of quality and safety. Novartis has worked closely with WHO under WHO s expedited procedure for evaluating pandemic influenza A(H1N1) 2009 vaccines to ensure rapid prequalification of its A(H1N1) 2009 influenza vaccines.

With WHO prequalification for all three of our A(H1N1) 2009 vaccines, we have expanded our commitment to contribute to the prevention of A(H1N1) 2009 influenza in all countries around the world, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics.

Prequalification of the adjuvanted vaccines is an important milestone to increase vaccine supply due to the proven antigen and dose sparing potential of the MF59 adjuvant. It is the only oil-in-water adjuvant supported by more than 12 years of post-marketing safety data that includes commercial distribution of more than 45 million doses. The adjuvant has also been studied in randomized clinical trials and observational studies involving 124,000 individuals including children, adults, and elderly; and was first licensed in the seasonal influenza vaccine Fluad® in Italy in 1997. Fluad is currently licensed in Europe for use in individuals 65 years of age and older.

Novartis recognizes the public health need for better access to medicines and vaccines in developing countries. Novartis is working closely with developing countries and international health agencies to find sustainable solutions for effective distribution of essential medicines for diseases such as malaria, meningitis, tuberculosis and leprosy.

**About Celtura®**

Celtura is an innovative adjuvanted, cell culture-based, inactivated subunit influenza vaccine indicated for active immunization of persons six months of age and older against influenza disease caused by the novel pandemic A(H1N1) 2009 influenza virus. Celtura was approved for use in both Germany and Switzerland in November 2009, and Novartis is also seeking approval in a number of other countries.

**About Focetria®**

Focetria is an adjuvanted, egg-based, inactivated subunit influenza vaccine indicated for active immunization of persons six months of age and older against influenza disease caused by the novel pandemic A(H1N1) 2009 influenza virus. Focetria was approved by the European Union on September 29, 2009, for use in all 27 member states of the European Union, plus, by extension, in Iceland, Norway and Liechtenstein through the European Economic Area (EEA) Agreement. It is also licensed in a variety of other countries including Turkey, Switzerland, Tunisia and Croatia.

**About Novartis A(H1N1) vaccine from the Fluvirin® platform**

This vaccine is an unadjuvanted, egg-based, inactivated subunit influenza vaccine indicated for active immunization of persons four years of age and older against influenza disease caused by the novel pandemic A(H1N1) 2009 influenza virus. The vaccine was approved for use in the US by the US Food and Drug Administration on September 15, 2009.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, commitment, seeking approval, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Novartis A(H1N1) vaccines, 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 A(H1N1) vaccines will be approved for sale in any additional countries. Nor can there be any 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 A(H1N1) vaccines could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing difficulties or delays, including continued unexpected difficulties with seed virus yields, and 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 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**

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| Date: December 21, 2009 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |