NOVARTIS AG
Form 6-K
September 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 September 25, 2009

(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

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

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

Novartis A(H1N1) Pandemic Influenza vaccine Focetria® receives positive opinion from CHMP

- *Significant milestone in bringing pandemic influenza vaccines to market in Europe*

- *Novartis delivers first shipments of A(H1N1) vaccine to governments in Europe just three months after the WHO declaration of the pandemic*

- *Focetria formulated with MF59® adjuvant which can boost the body s immune response and increase protective antibody levels with less antigen than needed with non-adjuvanted vaccines*

Basel, September 25, 2009 Novartis announced today that Focetria®, the Novartis Influenza A(H1N1) 2009 monovalent vaccine, has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA). The positive opinion clears the way for European Union approval in all 27 Member States as well as in Iceland and Norway. Today s announcement marks a significant milestone in bringing a pandemic vaccine to market in Europe.

Focetria, the Novartis Influenza A(H1N1) 2009 monovalent vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons of six months of age and older against influenza disease caused by the novel pandemic A(H1N1) influenza virus. The pandemic vaccine has been developed using traditional influenza manufacturing processes in an egg-based formulation. Focetria contains MF59®, Novartis proprietary adjuvant, which has been added to boost the immune response in individuals receiving the vaccine. MF59 can elicit protective antibody levels with a lower dose, just 7.5 micrograms of viral antigen versus 15 micrograms in non-adjuvanted vaccines, potentially resulting in greater vaccine supply.

Novartis has already started first deliveries of pandemic vaccines under quarantine to governments in Europe, despite the initially low yields with the current production seed strain provided by the World Health Organization (WHO). A new seed strain could provide higher volumes.

Only three months after the declaration of the pandemic by the WHO, Novartis was able to ship the first batches of our pandemic vaccine under quarantine to governments in Europe pending EU approval, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. This CHMP positive opinion paves the way for EU approval, which will allow governments to begin their vaccination campaigns with the goal of reaching more patients before the rapidly spreading virus reaches them. Several recent clinical trials suggest that just one dose of pandemic vaccine can protect healthy adults, which means that now the vaccine can be provided to more people than if two doses were needed.

Focetria was previously approved by the EU in May 2007 as a mock-up file to be used once the WHO declared a pandemic. This previous approval was based on clinical studies involving the MF59 adjuvant and different influenza strains with pandemic potential, including H5N1 and H9N2.

Novartis also plans to begin delivery of its Fluvirin® A(H1N1) monovalent vaccine to the US market by early October. The US Food and Drug Administration approved this vaccine on September 15, 2009. Data derived from recent clinical trials of Fluvirin conducted in Costa Rica indicate that a single-dose regimen is as effective as a two-dose regime in healthy adults ages 18-64 suggesting the potential to extend A(H1N1) vaccine supply further to support public health efforts. The trial was conducted in 784 healthy adults.

About MF59®

Novartis proprietary MF59 adjuvant has an established safety profile, supported by more than 12 years of clinical safety data and more than 40 million doses of commercial use in Europe. The adjuvant has been studied in clinical trials involving more than 26,000 people, including children, and has been licensed for use in people 65 years of age and over in the seasonal influenza vaccine, Fluad®, since 1997 in the European Union. Fluad is not licensed for sale in the U.S.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, potentially, could, will, suggest, potential, plans, suggesting, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Novartis A(H1N1) vaccines, potential production timing and volumes for such vaccines or regarding potential future revenues from such 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 A(H1N1) vaccines will be approved for sale in any market. Nor can there be any guarantee that A(H1N1) vaccines will be produced by any particular date, or in any particular volumes. Nor can there be any guarantee that A(H1N1) vaccines will achieve any particular levels of revenue in the future. In particular, management s expectations regarding 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 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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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

Paul Newman
Novartis Vaccines and Diagnostics
+1 (617) 871 7931 (direct)
+1 (617) 710 8953 (mobile)
paulc.newman@novartis.com

email: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Ruth Metzler-Arnold	+41 61 324 9980	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
John Gilardi	+41 61 324 3018	Jill Pozarek	+1 212 830 2445
Thomas Hungerbuehler	+41 61 324 8425	Edwin Valeriano	+1 212 830 2456
Isabella Zinck	+41 61 324 7188		

e-mail: 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: September 25, 2009

By: /s/ MALCOLM B. CHEETHAM

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