NOVARTIS AG
Form 6-K
November 24, 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 November 24, 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

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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

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- Investor Relations Release -

Novartis inaugurates large-scale US based cell-culture influenza vaccine manufacturing facility

- *Total investment of nearly USD 1 billion through a partnership between Novartis and the US Department of Health and Human Services*

- *Inauguration marks important milestone in using modern biotechnologies for flu vaccine production to replace the 50 year-old egg-based process*

- *Facility designed to supply 150 million doses of pandemic vaccine within 6 months of influenza pandemic declaration*; *facility ready to respond to a pandemic as early as 2011 if licensed in an emergency*

Basel, November 24, 2009 Today, Novartis officially inaugurated the US s first ever large-scale flu cell culture vaccine and adjuvant manufacturing facility in Holly Springs, North Carolina. The facility is a result of a partnership between Novartis and the US Department of Health and Human Services (HHS). It is the first of its kind in the United States and highlights an important milestone in efforts to improve influenza vaccine manufacturing technology in the US and enhance domestic pandemic preparedness.

We are proud to be one of the first companies to bring influenza cell culture as well as adjuvant technology to the United States, said Daniel Vasella, CEO and Chairman of Novartis. We have seen a great need to invest into new technologies for flu vaccines that will allow for quicker and more reliable production capacity. We are pleased to be working closely with the US government to build a world-class, state of the art manufacturing facility in the US that will change the way we manufacture influenza vaccines in the future.

The total investment in the facility is nearly USD 1 billion, through a partnership between Novartis and HHS to support the design, construction, validation and licensing of the manufacturing facility in Holly Springs.

The operations at this facility will use modern, cell culture-based manufacturing technology. Cell culture-based production operations are cleaner, can be scaled up more quickly to respond to a pandemic and do not rely on eggs for rapid response to a pandemic. Cell culture technology for influenza vaccines is not yet approved in the US, however part of the HHS contract support for Holly Springs includes funding for the development of a flu cell culture vaccine. If licensed in an emergency, the facility will be ready to respond to a pandemic as early as

2011. The plant is planned to be running at full scale commercial production in 2013.

Novartis already operates a cell culture-based manufacturing plant in Marburg, Germany. It is licensed to produce a seasonal cell culture-based influenza vaccine, Optaflu®, which is approved in all 27 member states of the European Union as well as in Iceland and Norway. It currently produces Celtura®, a H1N1 pandemic vaccine licensed in Germany and Switzerland.

The Novartis Holly Springs facility can also start producing MF59®, the Novartis proprietary adjuvant, as early as December 2009. Although not yet approved in the US, studies with adjuvants are currently underway in the US. Results of the most recent clinical trials conducted with the Novartis MF59 adjuvanted cell culture-based vaccine have shown that it is possible to induce protective antibody levels against A(H1N1) infection within two weeks of administration of a single low-dose adjuvanted vaccine. MF59 has also been shown to provide cross-protection across similar strains of a H5N1 virus, which is an additional important element for a pre-pandemic vaccine given that mutations are a common feature of emerging influenza strains.

As part of its partnership with HHS, Novartis is responsible for, among other things, pre-construction document development, land use and zoning, construction, commissioning, validation and licensing of the facilities with the goals of regulatory licensure, manufacture and release of seasonal and pre-pandemic vaccine, as well as provision for pandemic vaccine supply in the event of a pandemic or other vaccines or biologicals in the event of an emergency for an emerging infectious disease. The partnership also requires Novartis to provide two commercial-scale annual lots of pre-pandemic vaccine for a minimum of three years. In addition, HHS has the right to exercise options to purchase additional influenza vaccine over 17 years.

About MF59®

Novartis proprietary MF59 adjuvant has an established safety profile, supported by more than 12 years of clinical safety data and more than 45 million doses of commercial use in Europe. The adjuvant has been studied in clinical trials involving more than 33,000 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. Novartis also produces two A(H1N1) vaccines, Focetria® and Celtura, which contain MF59 and are available outside the US. Currently, there are no approved vaccines in the United States that contain MF59.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as as early as, will, future, planned, can similar expressions, or by express or implied discussions regarding the potential completion of the production facility at Holly Springs, the timing of potential commencement of and continued successful production of vaccines and adjuvants at Holly Springs, regarding the potential marketing approval cell-culture influenza vaccines, regarding the amounts to be paid by the government under the agreement described in this release, or regarding potential future revenues from vaccines produced at Holly Springs. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results at the Holly Springs facility to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that we will complete the Holly Springs facility, commence production there, or successfully continue production of vaccines there. Nor can there be any guarantee that any of the products expected to be produced at the Holly Springs facility will be approved for sale in any market. Neither can there be any guarantee that we will be paid the full amount referred to in this release. Neither can there be any guarantee that vaccines and adjuvants to be produced at Holly Springs will achieve any particular levels of revenue in the future. In particular, management s expectations regarding the Holly Springs production facility and vaccines produced there could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected construction difficulties or delays; unexpected production difficulties or delays, including difficulties or delays relating to the novel cell-culture production technique to be employed there; 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.

This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No s. HHSO100200600012C, HHSO100200700030C, HHSO100200900101C.

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: November 24, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting