NOVARTIS AG
Form 6-K
November 10, 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 5, 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

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- Investor Relations Release -

Novartis receives regulatory approval in Germany for Celtura®, a cell culture-based Influenza A(H1N1) pandemic vaccine

- *Approval marks an important milestone in the process of replacing 50 year-old egg-based flu vaccine production with modern biotechnology*

- *Clinical trials in more than 1,850 individuals across all age groups show strong efficacy, that can induce immune responses associated with protection against influenza in individuals from 3 to 50 years of age with immune responses*

- *Novartis continues to pursue registration of Celtura in other major countries*

Basel, November 5, 2009 Novartis announced today that it received approval from the German regulatory authorities for its adjuvanted cell culture-based Influenza A(H1N1) 2009 monovalent vaccine, Celtura®. Novartis continues to pursue registration in other major countries, including Japan and Switzerland.

Celtura is manufactured in Marburg, Germany and is an MF59® adjuvanted inactivated influenza virus vaccine indicated for active immunization of persons six months of age and older against influenza disease caused by the novel pandemic A(H1N1) influenza virus. The vaccine contains 3.75 micrograms (ug) of antigen and 1.25 ml of MF59®. It will be offered in multi-vial doses and in single pre-filled syringes.

Clinical studies conducted with more than 1,850 subjects evaluated Celtura s tolerability and immunogenicity. The studies showed that even with the lowest antigen content (3.75 ug) a single Celtura dose can induce immune responses associated with protection against influenza in individuals from 3 to 50 years of age. Safety and tolerability profiles were as expected. Local injection site (redness, swelling and pain) and systemic complaints of mild fever, headache and fatigue were the most frequent side effects reported.

Celtura uses a validated cell culture line for production of viral antigen components rather than traditional chicken eggs. The technology has previously been licensed in Europe for the production of the seasonal flu vaccine, Optaflu®.

Our modern cell culture technology can enable a faster start-up of vaccine manufacturing, offering the ability to respond more quickly to future pandemic threats , said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. We quickly ramped up capacity at our licensed cell culture facility in Marburg, Germany to respond to the need for a pandemic vaccine. Also we are close to completion of a second cell culture-based influenza vaccine manufacturing site in the US(1), which is being built in partnership with the US Department of Health and Human Services (HHS).

MF59 is an adjuvant with an established safety profile supported by more than 12 years of clinical safety data in Europe and more than 45 million doses of commercial use in the influenza vaccine Fluad® (licensed in Europe but not the US).

Novartis has already begun delivery of the company s egg-based pandemic vaccines, Fluvirin® A(H1N1) monovalent vaccine to the US, and Focetria® A(H1N1) monovalent vaccine to countries around the world. The US Food and Drug Administration approved the Fluvirin A(H1N1) vaccine on September 15, 2009, and the EMEA approved the Focetria A(H1N1) vaccine on September 29, 2009.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as continues to pursue, can, potentially, offering the ability, 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 influenza 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 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.

References

(1) 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. HHSO100200900101C.

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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 5, 2009

By: /s/ MALCOLM B. CHEETHAM

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