NOVARTIS AG
Form 6-K
September 04, 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 3, 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

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- Investor Relations Release -

Novartis MF59® adjuvanted cell culture-based vaccine shows strong immune response in A(H1N1) clinical trials

- *First pilot trial of investigational A(H1N1) vaccine with 100 subjects indicates strong, potentially protective, immune response in 80% of subjects after one dose, more than 90% after two doses.*

- *MF59® adjuvanted cell culture-based A(H1N1) vaccine was well tolerated, pain at the injection site the most frequent adverse event.*

- *Larger pivotal trials with both cell culture and traditional egg based vaccines under way to include more than 6000 adults and children.*

Basel, September 3 2009 A pilot trial of Novartis adjuvanted cell culture-based A(H1N1) vaccine(1) indicates that the swine flu vaccine elicited a strong immune response and was well tolerated. The trial was run by the UK s University of Leicester and University Hospitals of Leicester. The vaccine, to be called Celtura®, was tested with 100 healthy volunteers, aged between 18 and 50.

The trial evaluated the tolerability and immunogenicity of the vaccine. Different schedules and timing between vaccinations were tested. The vaccine schedule comprised one or two doses of 7.5µg MF-59® adjuvanted surface-antigen A/California/2009 vaccine derived from cell-culture. Results showed that the serum antibody responses were highest among subjects who received two doses of vaccine, however a single vaccine dose also induced responses associated with protection against influenza. Hemagglutination-inhibition titres reached 1:40 or greater in 80 percent and more than 90 percent of those receiving one dose and two doses respectively. These would satisfy the immunogenicity criteria as set out by European and US regulators. The findings showed that it is possible to induce protective antibodies against A(H1N1) infection within two weeks of administration of a single low-dose adjuvanted vaccine. Non-adjuvanted formulations were not evaluated in the study.

Additional pivotal clinical trials, with larger numbers of subjects and sponsored by Novartis, are already under way around the world. They will include more than 6000 adults and children.

The pilot trial results are encouraging, said Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. The study suggests that while two doses seem to provide better protection, one dose of our adjuvanted Celtura vaccine may be sufficient to protect adults against the swine flu.

This is important information for public health authorities who prepare for vaccination in the coming months with limited vaccine supply.

The pilot trial was led by Dr. Stephenson of the Department of Infection, Immunity and Inflammation at the University of Leicester. He is a clinical senior lecturer at the University, and a consultant in infectious diseases at the University Hospitals of Leicester NHS Trust.
Dr. Stephenson said the aim of the trial was to find out how many doses and what type of vaccine is needed to give protection. These initial results should help to plan vaccination campaigns in the autumn, including doses and timings. We concluded that the MF59-adjuvanted A(H1N1) vaccine of low antigen content was well tolerated and generated antibody responses associated with protection against influenza, even after a single dose.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, to include, will, encouraging, suggests, may, should, plan , or similar expressions, or by express or implied discussions regarding potential marketing approv for an influenza A(H1N1) vaccine, potential production timing and volumes for such a vaccine or regarding potential future revenues from such a vaccine. 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 influenza A(H1N1) vaccines will be approved for sale in any market. Nor can there be any guarantee that influenza A(H1N1) vaccines will be produced by any particular date, or in any particular volumes. Neither can there be any guarantee that influenza A(H1N1) vaccines will achieve any particular levels of revenue in the future. In particular, management s expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data from the ongoing trials of the A(H1N1) vaccine, and unexpected additional analysis of existing clinical data regarding the vaccine; 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, and unexpected difficulties with the established egg-based manufacturing process; competition in general; government, industry and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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 Novartis division 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

Footnote

(1) Development of Novartis cell-based influenza vaccine, construction of the cell-based influenza manufacturing facility at Holly Springs, NC and purchase of H1N1 antigen and adjuvant are being funded in whole or in part with Federal funds from the Office of Public Health Emergency Preparedness, Office of Research and Development Coordination, under Contract Numbers HHSO100200600012C, HHSO100200900101C and HHSO1002008000721, respectively.

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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: September 3, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting