NOVARTIS AG
Form 6-K
November 17, 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 17, 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 Influenza A(H1N1) 2009 vaccine US interim data show lower doses of antigen may suffice to generate a protective immune response against A(H1N1)

- *Interim clinical data from approximately 4,000 individuals suggest that half a dose of the currently US-approved Novartis unadjuvanted Influenza A(H1N1) 2009 vaccine met immunogenicity criteria in adults and the elderly*

- *Data also show that Novartis MF59® adjuvant was well tolerated and could potentially quadruple the Novartis A(H1N1) 2009 influenza vaccine supply*

- *MF59® adjuvant has an established safety profile supported by clinical data from more than 33,000 study participants and 12 years of real life safety data with more than 45 million doses of influenza vaccine administered since 1997 in Europe*

Basel, November 17, 2009 Novartis announced today new interim data from ongoing clinical trials demonstrating that a single 7.5µg dose of the company s influenza A(H1N1) 2009 unadjuvanted vaccine, half of the currently-approved US dose, fulfilled immune response criteria associated with protection in adults and the elderly (≥65 years of age).

The data also showed a single 3.75µg dose of MF59-adjuvanted A(H1N1) 2009 vaccine met serologic protection criteria against influenza A(H1N1) in children ages 3 to 8, adults ages 18 to 64, and the elderly. All A(H1N1) 2009 influenza study vaccines were manufactured using the Novartis established seasonal Fluvirin® manufacturing platform. Novartis has discussed these new data with the US Food and Drug Administration (FDA) and is performing additional statistical analysis suggested by the agency. It is still under evaluation whether the antigen content per dose can be reduced in the US.

Current US guidelines for A(H1N1) 2009 vaccine use state that adolescents, adults and the elderly are required to receive one 15µg dose to achieve adequate protective antibody levels against the A(H1N1) virus, and children 9 years of age and under are required to receive two 15µg doses four weeks apart.

These promising data suggest that many more people could potentially be vaccinated with our current vaccines supply, protecting more people earlier against the current pandemic, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. The data also confirms the antigen

sparing potential of our proprietary adjuvant, MF59®. The vaccines output of our Liverpool, U.K., based flu manufacturing facility, fully dedicated to the US since the emergence of the pandemic, could be quadrupled if vaccines are adjuvanted.

These interim data were generated from pivotal clinical studies designed to evaluate the immunogenicity, safety and reactogenicity of both MF59-adjuvanted and unadjuvanted, inactivated novel swine origin A(H1N1) 2009 monovalent subunit influenza virus vaccine in 4,080

US subjects. In the pediatric trial, the findings are based on 80% of first dose data from 1,360 subjects ages 3 to 8 at day 22. In the adult trial, the findings are based on 95% of first dose data at day 1 and day 8 and approximately 40% of first dose data at day 22 from 1,360 adult subjects and 1,360 elderly subjects. Second dose data and data in ages 6-36 months of age are expected in December 2009.

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.

Novartis has been contracted by the US Department of Health and Human Services (HHS) to produce 90 million doses of MF59 by the end of November.(1)

About A(H1N1) 2009 Vaccine

Novartis influenza A(H1N1) 2009 monovalent vaccine, manufactured using the established seasonal Fluvirin platform, is an inactivated influenza virus egg-derived vaccine indicated for active immunization of persons 4 years of age and older against influenza disease caused by pandemic A(H1N1) 2009 virus. The vaccine was approved by the FDA on September 15, 2009 as an unadjuvanted 15µg dose.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, suggest, could, potentially, promising, potential, expected, or similar expressions, or by express or implied discussions regarding regarding potential additional marketing approvals for Novartis A(H1N1) vaccines and adjuvants, potential new indications or labeling for Novartis A(H1N1) vaccines and adjuvants, potential future deliveries of influenza vaccines and adjuvants, or regarding potential future revenues from Novartis A(H1N1) vaccines and adjuvants. 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 with Novartis A(H1N1) vaccines and adjuvants to be materially different from any future results, performance or achievements expressed or implied by such statements. Novartis A(H1N1) vaccines will achieve any additional marketing approvals. Nor can there be any guarantee that Novartis A(H1N1) vaccines and adjuvants will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Novartis will successfully meet its delivery obligations for its A(H1N1) vaccines and adjuvants. Neither can there be any guarantee that Novartis A(H1N1) vaccines and adjuvants will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Novartis A(H1N1) vaccines and adjuvants 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.

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. HHS100200800072I.

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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 17, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting