NOVARTIS AG
Form 6-K
July 02, 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 June 30, 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 Complete Response letter from the US Food and Drug Administration for its investigational vaccine Menveo®

Cambridge, MA, June 30, 2009 Novartis Vaccines and Diagnostics received feedback from the US Food and Drug Administration (FDA) in the form of an initial regulatory determination on the Biologics License Application (BLA) for the investigational vaccine Menveo®.

The FDA has requested additional information on the clinical and the CMC (Chemistry Manufacturing and Control) sections of the BLA. No new clinical trials are required, and it is expected that Novartis will be able to respond to all questions fully in 2009. The BLA was submitted on August 28, 2008 for use of Menveo in subjects age 11 - 55.

In clinical trials, Menveo has been shown to elicit a protective immune response against four of the most common serogroups A, C, W-135 and Y of *Neisseria meningitides*, also known as meningococcus. These serogroups can cause potentially deadly bacterial infections and account for most cases of meningococcal disease worldwide.

Meningococcal disease is a devastating illness that can result in rapid death or have long-lasting repercussions for survivors and their families, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. We are dedicated to applying our industry-leading technology and expertise to further the development of Menveo and other vaccines that elicit robust, long-lasting, protective immune responses for all age groups at risk.

About the Novartis Vaccines global meningococcal franchise

Menveo is based on the same proprietary technology Novartis Vaccines pioneered to produce Menjugate®, a meningococcal serogroup C conjugate vaccine approved outside the US since 2000 for use in individuals from age 2 months through adulthood.

Studies have reported that Menveo generates a robust immune response against the four vaccine-preventable serogroups, A, C, W-135 and Y in people across age groups from infancy to adulthood. A Phase II study in infants published in the January 9, 2008, issue of the *Journal of the American Medical Association* reported that Menveo is the first meningococcal vaccine candidate to elicit a robust immune response in infants(1). There is no vaccine currently licensed in the US for use in infants.

Novartis Vaccines is a global leader in providing vaccines to protect against deadly meningococcal disease. Through industry-leading scientific expertise, the company is focused on extending critical meningococcal vaccines research. In addition to Menveo, Novartis Vaccines is developing a recombinant vaccine for its potential to provide broad coverage against multiple strains of serogroup B, for which no vaccine is currently available. The company has already distributed more than 26 million doses of Menjugate around the world and produced MenZB®, a vaccine against a strain of meningococcus B specific to a recent outbreak in New Zealand.

About meningococcal disease, a leading cause of bacterial meningitis

Meningococcal disease can manifest as bacterial meningitis an infection of the protective coverings of the brain and spinal cord or meningococcemia a bloodstream infection(2). It is caused by the bacterium *Neisseria meningitidis (N. meningitidis).* The symptoms, which can include sudden onset of fever, rash, headache and stiff neck, can progress rapidly. Even with early and appropriate treatment, between 10% and 14% of meningitis cases are fatal, typically within 24 to 48 hours(4),(5). For those who survive, as many as 19% suffer serious long-term consequences such as deafness, neurological damage or limb loss.

Because invasive meningococcal disease can progress so rapidly, high levels of circulating antibodies are critical for protection. Immune memory typically takes up to five days to develop, so there often is not enough time for immune memory to mount a protective response(3).

Five serogroups cause the majority of meningococcal disease worldwide: A, B, C, W-135 and Y(1). Distribution of serogroups varies widely from geographic region to region and changes over time. In the US, the prevalence of serogroup Y has increased over the last few years (from 9% of reported cases in 1990-92 to 39% in 2006)(3). Serogroups B and C are predominant in Europe. While Asia has primarily seen serogroup A, recent outbreaks of serogroup C have been noted. The dynamic and unpredictable nature of meningococcal disease epidemiology warrants a vaccine that offers broad serogroup protection(6).

For more information, please visit www.meningitis.com.

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, will, can, dedicated, potential, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Menveo or regarding potential future revenues from Menveo. 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 Menveo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Menveo will be approved for sale in any market. Nor can there be any guarantee that Menveo will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Menveo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including an unexpected inability to meet the requirements of the FDA: 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 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 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 AG 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 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 98,000 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) Snape, MD et al. Immunogenicity of a Tetravalent Meningococcal Glycoconjugate Vaccine in Infants: A Randomized Controlled Trial. Journal of the American Medical Association. 2008;299(2): 173-184

(2) Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook). 10th Edition, 2nd printing. February 2008 update. Available at: http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm

(3) Novartis Vaccines and Diagnostics, Scientific Platform: Meningococcal Diseases, Revised December 11, 2008

(4) Centers for Disease Control and Prevention. Prevention and Control of Meningococcal Disease Recommendations of the Advisory Committee on Immunization Practices. MMWR 2005; 54 (RR07): 1-21.

(5) World Health Organization. Meningococcal meningitis Fact sheet. May 2003. Available at: http://www.who.int/mediacentre/factsheets/fs141/en/

(6) Harrison, Lee H. Prospects for Vaccine Prevention of Meningococcal Infection, Clinical Microbiology Reviews: January 2006 : 142-16

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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: June 30, 2009

By: /s/ MALCOLM B. CHEETHAM

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