NOVARTIS AG
Form 6-K
March 19, 2010

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 March 18, 2010

(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
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Novartis receives approval in the European Union for Menveo®, first quadrivalent conjugate vaccine in the EU to help prevent meningococcal disease

- *Meningococcal disease is a major cause of bacterial meningitis and sepsis with high consequent disability and mortality rates worldwide(1)*

- *Dominant groups of meningococcal disease vary by country and region, and can change over time, making it an even more unpredictable disease(2)*

- *Menveo helps protect against four of the five major bacterial groups responsible for meningococcal disease*

- *One year after vaccination, more adolescents maintained protective immune response against three of the four groups when immunized with Menveo than with polysaccharide vaccine(3)*

Basel, March 18, 2010 Novartis announced today that the European Commission (EC) granted a Marketing Authorization for Menveo® (Meningococcal Group A, C, W135 and Y conjugate vaccine) in all 27 European member states. Menveo is indicated for the active immunization of adolescents (from 11 years of age) and adults at risk of exposure to *Neisseria meningitidis* groups A, C, W135 and Y, to prevent invasive disease. Menveo is the first conjugate vaccine commercially available in Europe that helps protect against four major groups of meningococcal disease. Novartis intends to submit additional data to the EMEA to support the use of Menveo in other age groups.

Meningococcal infection is a leading cause of bacterial meningitis an infection of the membrane around the brain and spinal cord and sepsis a bloodstream infection(4), (5). Meningococcal disease progresses rapidly and can lead to death within 24-48 hours of the first symptoms(6). Of those who survive, as many as one in five will suffer life-long complications such as brain damage, learning disabilities, hearing loss and limb loss(4).

Marketing approval for Menveo for people ages 11 and older is the culmination of 10 years of dedicated effort by Novartis Vaccines to provide a vaccine that can help protect against meningococcal disease, said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. Our priority is to advance the fight against meningitis through innovative vaccines that help save lives.

The majority of all meningococcal disease cases around the world can be attributed to five main groups called serogroups of the bacteria that cause meningococcal disease, *Neisseria meningitidis(2).* Importantly, dominant groups of meningococcal disease can vary by country and

region, and change over time, making it an even more unpredictable disease(2). The most effective way to prevent this deadly disease is through the use of a vaccine that offers protection against as many bacterial groups as possible(1).

Adolescents and young adults are at increased risk of contracting meningococcal disease, often because they start to encounter new situations and undergo changes in their lifestyles(5), (7). Other groups at increased risk of contracting meningococcal disease include travelers, military personnel and Muslim pilgrims traveling to the Hajj or Umrah(6).

Menveo was developed using conjugate technology, which was pioneered by Novartis Vaccines in the development of its meningococcal group C conjugate vaccine, Menjugate®. A conjugate vaccine is developed by attaching a polysaccharide antigen the key component of a vaccine that prompts the body to respond to infection to a carrier protein in order to enhance the body s immune response to the vaccine(7).

When utilized in a national immunization program, conjugate vaccines (such as those designed to help protect against Hib, pneumococcal and meningococcal group C disease) have reduced the number of people (both vaccinated and unvaccinated) who carry the bacteria that cause the disease(7c). Novartis is currently studying the long-term safety and immunogenicity of Menveo, and is considering clinical studies on carriage.

Menveo has been administered to more than 18,500 people and is currently in multiple Phase III clinical studies in infants and toddlers worldwide(8). The U.S. Food and Drug Administration (FDA) recently approved Menveo for use in 11-55 year olds.

Study Details

Marketing Authorization was based on data from a pivotal Phase III clinical trial and a non-inferiority study. In the non-inferiority study, immune response was assessed among adolescents 11-17 years of age. Menveo was shown to be non-inferior to a quadrivalent meningococcal polysaccharide vaccine (ACWY-PS) for all four meningococcal groups contained in the vaccine(3). At one year after vaccination, a higher proportion of adolescents who received Menveo had maintained a protective immune response against three of the four meningococcal groups (groups C, W135 and Y) than those who received ACWY-PS(3). Further, when evaluated in adults 56-65 years of age, Menveo was shown to be non-inferior to ACWY-PS in all four meningococcal groups contained in the vaccine and statistically superior for groups A and Y(3). The clinical significance of these findings is unknown.

Achieving and maintaining an immune response in adolescents is considered important because they are particularly susceptible to meningococcal disease and are more likely to carry the bacteria than other age groups(9). In addition, adolescents and young adults have relatively high death rates from meningococcal infection(10). A study in the United States found that nearly a quarter of meningococcal infections in 15- through 24-year-olds were fatal(10).

Meningitis often develops without warning, and progresses rapidly, making it a particularly dangerous disease(6), (11), said Chris Head, Chief Executive of the Meningitis Research Foundation, UK. Awareness of symptoms, understanding treatment and, above all, prevention with a vaccine that helps to protect against multiple groups of bacteria will help save lives and prevent devastating, lifelong after-effects.

About meningococcal disease

Most cases of meningococcal disease occur in previously healthy people without any warning(11). Even small changes in lifestyle such as going out to clubs, travelling, smoking, going to college or military duty can increase the likelihood to become a carrier of meningococcal bacteria and the chance of a person contracting meningococcal disease(7). The World Health Organization (WHO) and several national governments recommend the use of meningococcal vaccination for

people considered to be at increased risk for developing meningococcal disease, such as adolescents, travelers to areas known for outbreaks, military personnel and Muslim pilgrims travelling to the Hajj or Umrah(6), (7).

Because the initial symptoms of meningococcal disease can be non-specific and flu-like(12), it can be difficult for health care professionals to diagnose early. Classic symptoms, such as neck stiffness and petechial rash, do not appear until relatively late in the illness 13 to 22 hours after the first symptoms appear(13).

According to the WHO, approximately 5-10 percent of those who contract meningococcal disease will die, even if they are diagnosed and receive treatment(6). Of those who survive meningococcal disease, as many as one in five will suffer life-long complications, such as brain damage, learning disabilities, hearing loss and limb loss(4).

Infants are the most vulnerable population and represent the greatest unmet need. About 6-10 percent of children under 12 months of age who contract meningococcal disease will die(14).

About Novartis Vaccines global meningococcal franchise

Menveo vaccine is based on the same proprietary technology Novartis Vaccines pioneered to produce Menjugate®, a meningococcal serogroup C conjugate vaccine approved outside the U.S. since 2000 for use in individuals from 2 months of age through adulthood. The company has already distributed more than 41 million doses of Menjugate around the world. Novartis also produced MenZB®, a vaccine against a strain of meningococcus B specific to an outbreak in New Zealand.

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 developing Menveo vaccine, Novartis Vaccines is developing a recombinant protein vaccine for its potential to provide broad coverage against multiple strains of serogroup B, for which no vaccine is currently available.

Important Safety Information

Menveo is indicated for active immunization of adolescents (from 11 years of age) and adults at risk of exposure to *Neisseria meningitidis* groups A, C, W-135 and Y, to prevent invasive disease.

Menveo should not be administered to individuals with known hypersensitivity to any component of Menveo or other meningococcal vaccines, or other vaccines containing derivatives of *Corynebacterium diphtheriae*. Because of the risk of hematoma, Menveo should not be administered to individuals with any bleeding disorder, such as hemophilia or thrombocytopenia, nor to persons receiving anticoagulant therapy, unless the potential benefit outweighs the risk of administration. Menveo should not be administered to people who have an acute severe febrile illness, although a mild fever of short duration is not a contraindication. Due to the absence of supporting data, the decision to administer Menveo to pregnant women should be evaluated according to the risk of meningococcal infection.

The most common local adverse reactions to Menveo include injection site pain, erythema, and induration. The most common systemic adverse reactions include headache, myalgia, malaise, nausea, arthralgia, chills, rash and fever. Some reactions may be severe.

Vaccination with Menveo may not protect all individuals. Patients who are immunocompromised or receiving immunosuppressive therapy may have an inadequate response to vaccination.

Before administering Menveo, please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, intends, will, can, priority, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo, potential future approvals of additional Novartis vaccines or regarding potential future revenues from such 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 Menveo will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that any additional vaccines will be approved for sale in any markets. Neither can there be any guarantee that Menveo or any additional vaccines will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Menveo or any additional vaccines could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 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, 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 these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 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) World Health Organization. Meningococcal Position Paper. Weekly Epidemiological Record No. 44, 2002, 77, 329-340. Available at: http://www.who.int/immunization/wer7740meningococcal_Oct02_position_paper.pdf. Accessed on January 19, 2010.

(2) Schaffner, W. et al. The Changing Epidemiology of Meningococcal Disease Among US Children, Adolescents, and Young Adults. National Foundation for Infectious Diseases. November 2004. Available at: http://www.nfid.org/pdf/meningitis/FINALChanging_Epidemiology_of_Meningococcal_Disease.pdf. Accessed on January 19, 2010.

(3) Jackson, L. et al. (2009). A randomized trial to determine the tolerability and immunogenicity of a quadrivalent meningococcal glycoconjugate vaccine in healthy adolescents. *The Pediatric Infectious Disease Journal* 2009: 28(2), 86-91.
(4) 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. Accessed on January 19, 2010.
(5) Centers for Disease Control and Prevention. Meningitis: Questions & Answers. June 2009 update. Available at: http://www.cdc.gov/meningitis/about/faq.html. Accessed on January 19, 2010.
(6) World Health Organization. Meningococcal Meningitis Fact Sheet. May 2003. http://www.who.int/mediacentre/factsheets/fs141/en/print.html. Accessed on January 19, 2010.
(7) 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. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm. Accessed on January 19, 2010.
(8) Novartis Data on File.
(9) National Advisory Committee on Immunization. (2009). Update on the invasive meningococcal disease and meningococcal vaccine conjugate recommendations. Canada Communicable Disease Report, April 2009, Vol. 36. Available at: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09pdf/acs-dcc-3.pdf. Accessed on January 19, 2010.
(10) Harrison, L. et al. (2001). Invasive meningococcal disease in adolescents and young adults. *Journal of the American Medical Association* 2001: 286(6), 694-699. Available at: http://jama.ama-assn.org/cgi/reprint/286/6/694. Accessed on January 19, 2010.
(11) Pollard, A. J. and Maiden, C.J. (Eds.) (2001). Meningococcal Disease: Methods and Protocols. Totowa, NJ: Humana Press, Inc.
(12) Mayo Foundation for Medical Education and Research. Meningitis. August 2008. Available at: http://www.mayoclinic.com/health/meningitis/DS00118. Accessed on January 19, 2010.
(13) Thompson, M.J. et al. (2006). Clinical recognition of meningococcal disease in children and adolescents. *Lancet, 367*(9508), 397-403. Available at: http://www.ncbi.nlm.nih.gov/pubmed/16458763. Accessed on January 19, 2010.
(14) Cohn, A. et al. (2010). Changes in Neisseria meningitidis disease epidemiology in the United States, 1998-2007: Implications for prevention of meningococcal disease. *Clinical Infectious Diseases* 2010, 50(2): 184-191.

# # #

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Beth Birke
Novartis Vaccines Communications
+1 (617) 871 4281 (direct)
+1 (617) 803 4359 (mobile)
nvd.communications@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Ruth Metzler-Arnold	+41 61 324 9980	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
John Gilardi	+41 61 324 3018	Jill Pozarek	+1 212 830 2445
Thomas Hungerbuehler	+41 61 324 8425	Edwin Valeriano	+1 212 830 2456
Isabella Zinck	+41 61 324 7188		

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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: March 18, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting