

NOVARTIS AG  
Form 6-K  
December 18, 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 December 18, 2009**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Yes:

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**- Investor Relations Release -**

**Novartis meningococcal vaccine Menveo® recommended for approval in the European Union for prevention of disease in adolescents and adults**

- *Investigational vaccine Menveo demonstrates a protective immune response in four of the five major bacteria groups responsible for meningococcal disease*
- *Meningococcal disease is a major cause of bacterial meningitis and sepsis with high consequent disability and mortality rates worldwide*

**Basel, December 18, 2009** Novartis Vaccines announced today that Menveo® (Meningococcal Group A, C, W-135 and Y-CRM Conjugate Vaccine) has received a Positive Opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The investigational conjugate vaccine is recommended for 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 designed to help protect against four of the five major groups of meningococcal bacteria, which are leading causes of bacterial meningitis – an infection of the membrane around the brain and spinal cord – and sepsis – a bloodstream infection<sup>1a, 2</sup>.

The CHMP recommendation serves as the basis for a European Commission licensing Decision. The CHMP is recommending that the European Commission grant Marketing Authorization for Menveo in all 27 European Union (EU) countries, which is expected during the first quarter of 2010. Regulatory review for Menveo by the US Food and Drug Administration is ongoing.

Upon licensure, Menveo is expected to be the first conjugate vaccine to be commercially available in Europe to help protect against four major groups of meningococcal bacteria. Meningococcal disease is a sudden, life-threatening illness that can lead to death within 24 to 48 hours of the first symptoms<sup>3a, 4a, 5a</sup>. Of those who survive, as many as one in five will suffer life-long after effects, such as brain damage, learning disabilities, hearing loss and limb loss<sup>1b</sup>.

The Committee's positive recommendation of Menveo is a significant advance in the fight against meningococcal disease, said Professor Ray Borrow who heads the Health Protection Agency's Vaccine Evaluation Unit in the UK. Five groups of meningococcal bacteria cause the majority of meningococcal disease cases around the world<sup>3b</sup>. Since it is impossible to predict which meningococcal bacterial group one might come into contact with, a vaccine that offers effective protection against four of the groups should be extremely effective in preventing and controlling the disease. It is a welcome development.

This is an important milestone toward our vision to eradicate this devastating, deadly and unpredictable disease, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. We are confident that broad coverage with Menveo will eventually be available to all age groups.



Menveo was developed using conjugate technology, which was also used to develop Novartis Vaccines' 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. 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.

Adolescents are particularly susceptible to meningococcal disease and are more likely to carry the bacteria than other age groups<sup>3c</sup>. In addition, adolescents and young adults have relatively high death rates from meningococcal infection. A study in the United States found that nearly a quarter of meningococcal infections in 15- through 24-year-olds were fatal<sup>8</sup>.

Menveo has been administered to more than 18,500 people and is currently in multiple Phase III clinical studies in infants and toddlers worldwide.

#### **About meningococcal disease**

Meningococcal disease is a sudden, life-threatening illness that progresses rapidly and can lead to death within 24 to 48 hours of the first symptoms<sup>3a, 4a, 5a</sup>. 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<sup>1a, 2</sup>. The bacteria that cause meningococcal disease—*Neisseria meningitidis*—can be divided into groups. Five groups of meningococcus cause the majority of all meningococcal disease cases around the world<sup>4b</sup>.

Because the initial symptoms of meningococcal disease can be similar to flu-like symptoms<sup>10</sup>, 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—13-22 hours after the first symptoms appear<sup>11</sup>.

According to the World Health Organization (WHO), approximately 5-10 percent of those who contract meningococcal disease will die, even if they are diagnosed and receive treatment<sup>5c</sup>. Of those who survive meningococcal disease, as many as one in five will suffer life-long side effects, such as brain damage, learning disabilities, hearing loss and limb loss<sup>1b</sup>.

Infants are the most vulnerable population and represent the greatest unmet need<sup>4c</sup>. About 6-10 percent of children under 12 months of age who contract meningococcal disease will die<sup>9</sup>.

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 26 million doses of Menjugate around the world. Novartis also produced MenZB®, a vaccine against a strain of meningococcus B specific to a recent 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.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as recommendation, recommended, risk, should, recommending, expected, can, will, confident, anticipates, potential, or similar expressions, or by express or implied

discussions regarding potential approvals to market for Menveo or other vaccines, or regarding potential future revenues from Menveo or such other 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 or any other vaccine referred to in this release will be approved for sale in any market. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; 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 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>.

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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: December 18, 2009

By: /s/ MALCOLM B. CHEETHAM

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