

NOVARTIS AG  
Form 6-K  
May 06, 2008

## 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 May 6, 2008

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

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Yes:  No:

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**- Investor Relations Release -**

**Novartis Menveo® vaccine shows superior immune response against four types of meningitis disease in pivotal phase III trial**

- *First Phase III, head-to-head data show Menveo may offer greater protection for adolescents compared to Menactra\**
- *Novartis expects Menveo to be first quadrivalent meningococcal vaccine to protect from early infancy through adulthood*
- *More than 8 million infants and adolescents in the US and a significant number of children and travellers globally could benefit from Menveo(1)*

**Basel, May 6, 2008** New Phase III data for Menveo® (MenACWY-CRM) show that the vaccine produced a greater immune response against meningococcal serogroups A, C, W-135 and Y in adolescents 11-18 years of age compared to Menactra®. Infection with any of these four vaccine-preventable serogroups can lead to bacterial meningitis, an infection of the membrane around the brain and spinal cord, or sepsis, a serious infection of the blood stream.

Results of this first head-to-head trial of Menveo compared to Menactra, show that adolescents who were immunized with Menveo generated higher levels of antibodies against all four serogroups(2).

Notably for serogroup Y, among adolescents with low levels of immunity at the time of vaccination, 81% of subjects receiving Menveo generated a protective immune response vs. 54% with Menactra(2), as measured by the hSBA assay. Serogroup Y causes approximately 39% of meningococcal disease cases in the US(3).

To protect children against all major serogroups of meningococcal disease, we need vaccines that provide broad coverage and that can be used in all at-risk age groups, said Keith S. Reisinger, MD, MPH, Medical Director, Primary Physicians Research, Inc. Pittsburgh, PA. These data are encouraging because they show that Menveo may provide greater protection for the more than 8 million infants and adolescents in the US against these four vaccine-preventable serogroups than the currently available vaccine.

Menveo is an investigational quadrivalent meningococcal conjugate vaccine in Phase III clinical development by Novartis Vaccines. The data were presented at a late-breaker platform session on May 5 during the 2008 Pediatric Academic Societies (PAS) Annual Meeting in Honolulu, Hawaii.

Meningococcal disease, a leading cause of bacterial meningitis, is a rare but contagious and potentially life-threatening infection. Infants and adolescents have the highest rates of disease<sup>4a</sup>, which can be fatal. Each year approximately 1,400 to 2,800 cases of disease occur in the US<sup>4b</sup>, and

about 10-14 percent of patients die<sup>4c</sup>. The currently available vaccines are not licensed for use in infants, in whom the highest rates of meningococcal disease are observed. Phase II data published in the January 9, 2008, issue of the *Journal of the American Medical Association* demonstrated Menveo to be the first meningococcal vaccine to produce a strong immune response in infants<sup>(5)</sup>.

The US Centers for Disease Control and Prevention (CDC) recommends routine immunization with a quadrivalent meningococcal conjugate vaccine for all adolescents 11-18 years of age, college freshmen living in dormitories and people in other high risk groups who are two to ten or 19 to 55 years of age<sup>(6),(7)</sup>.

The patient need for vaccines for meningococcal disease remains substantial. We appear to be quickly realizing our goal of providing broad coverage against all serogroups of meningococcal disease across all age groups, said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. Given the broad range of age groups this vaccine is expected to protect, Menveo could truly fulfill an unmet need in the meningitis vaccine market.

#### **Study details(2)**

This Phase III trial involved more than 2,100 11-18 year olds who received a single vaccination with either Menveo or Menactra. One month after vaccination, geometric mean titers (a measure of immune response) for Menveo vs. Menactra were: serogroup A, 29 vs. 18; serogroup C, 59 vs. 47; serogroup W-135, 87 vs. 44; and serogroup Y, 51 vs. 18. Additionally, the percentage of participants who achieved a protective immune response, determined by a human serum bactericidal antibody titer (hSBA) > 1:8, with Menveo vs. Menactra was: serogroup A, 75% vs. 67%; serogroup C, 84% vs. 84%; serogroup W-135, 96% vs 88%; and serogroup Y, 88% vs. 69%. Similar results were seen in the large subset of sero-negative participants, who are the participants without any natural immunity to the bacteria before vaccination. The hSBA assay measures the body's protective immune response to the meningococcus based on the ability of antibodies to kill the bacteria.

#### **About Menveo**

These data build on previous studies that demonstrated Menveo generates a strong protective immune response against these four vaccine-preventable serogroups in people across age groups from infancy to adulthood. Novartis expects to submit a Biologics License Application (BLA) to the US Food and Drug Administration later this year.

Menveo is currently in multiple Phase III clinical trials involving infants, young children, adolescents and adults. The vaccine is based on the same technology Novartis pioneered to produce Menjugate<sup>®</sup>, a meningococcal serogroup C conjugate vaccine approved outside the US since 2000 for use in individuals from two months of age through adulthood.

Novartis is a global leader in providing vaccines to protect against the deadly meningococcal disease. In addition to developing Menveo, Novartis has already distributed more than 26 million doses of Menjugate around the world and produced MenZB<sup>®</sup>, a vaccine against a strain of meningococcus B specific to a recent outbreak in New Zealand. Novartis is also developing a recombinant vaccine to provide broad coverage against multiple strains of serogroup B, for which no vaccine is currently available.

**About meningococcal disease, a leading cause of bacterial meningitis**

Meningococcal disease can manifest as bacterial meningitis – an infection of the membranes around the brain and spinal cord – or sepsis, a bloodstream infection. 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, some cases are fatal, typically within 24-48 hours<sup>(8)</sup>. For those who survive, as many as 19 percent suffer serious long-term consequences such as deafness, neurological damage or limb loss<sup>4d</sup>.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as may, expects, and encouraging, potentially, can be, goal, expected, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or approvals for, or potential future sales of, Menveo or other vaccines currently in development by Novartis. Such forward-looking statements reflect the current views of Novartis 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 or any other vaccine currently in development by Novartis will be submitted or approved for any indications in any market. Nor can there be any guarantee that Menveo or any other vaccine, if approved, will achieve any particular levels of sales. In particular, management's expectations regarding Menveo 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; Novartis' ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG's Form 20-F on file with the U.S. 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 include influenza, 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 AG provides healthcare solutions that address the evolving needs of patients and societies. Focused on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

#### **References**

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\* Menactra is a registered trademark of Sanofi Pasteur.

**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: May 6, 2008

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting