

NOVARTIS AG
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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 14, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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:

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Yes: No:

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- Investor Relations Release -

In a Phase II study, Novartis Meningitis B vaccine has potential to produce a protective immune response in infants(1), the age group most at risk

- *Data show Novartis Meningitis B (MenB) vaccine has potential to be first vaccine to provide broad protection to infants against meningococcal B infections*
- *The meningococcal B strain causes 72% of meningococcal disease in Europe and is a major cause of the disease in other regions of the world*
- *Novartis MenB vaccine and Novartis Menveo® (MenACWY-CRM) vaccine on track to establish strong portfolio of meningitis vaccines*

Basel, May 14, 2008 New data for the investigational recombinant meningococcal group B vaccine developed by Novartis Vaccines, support its promise as the first potentially broad coverage vaccine capable of protecting infants against the meningococcal B strain. Prevention of meningococcal B infections remains a high medical need to protect infants and children worldwide from infection of this often deadly disease.

The meningococcal B strain is a leading cause of bacterial meningitis throughout the world⁽²⁾, particularly among infants⁽³⁾, accounting for 72 percent of meningococcal disease in Europe in 2006⁽⁴⁾. The new Phase II data for the novel Novartis MenB vaccine were presented at the European Society for Paediatric Infectious Diseases (ESPID) annual meeting in Graz, Austria on May 14, 2008.

The prospect of one vaccine that protects infants worldwide against meningococcal serogroup B would be a key achievement in global disease prevention of our time, said Ray Borrow, PhD, MRCPATH, Head, Vaccine Evaluation Unit, Health Protection Agency, UK. Of those infected with the meningococcal B strain, there is a strong likelihood that the bacterium contains at least one of the antigens included in the Novartis MenB vaccine. These new findings tell us that the vaccine is likely to kill strains that contain the vaccine's antigens.

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According to new Phase II study results, a series of three immunizations with the Novartis MenB vaccine starting at two months of age produced a protective immune response in infants, as evaluated by a biomarker of clinical protection. One month after the third dose, the percentage of subjects achieving a protective immune response against strains representing multiple antigens included in the Novartis MenB vaccine were 89%, 96% and 85%. A fourth dose given at 12 months of age also resulted in 100%, 98% and 93% of subjects achieving a protective immune response and was indicative of an immune memory response⁽¹⁾. The vaccine contains multiple bacterial surface proteins or antigens that are believed to be found in most meningococcal B strains responsible for the disease globally.

Novartis scientists pioneered an innovative approach called reverse vaccinology to develop the Novartis MenB vaccine. By first decoding the entire genetic makeup of a pathogenic meningococcal serogroup B strain, Novartis discovered 600 novel proteins. Reproduced through genetic engineering for further investigation, the vaccine contains multiple antigens that showed the greatest ability to stimulate the immune system to kill bacteria from a panel of 85 strains of meningitis B representative of global and temporal diversity.

There is a strong medical need for an effective vaccine to prevent meningitis B infections, and our commitment to developing new vaccine technologies may soon provide a broad spectrum meningitis B vaccine, said Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. Through our scientific expertise, Novartis is rapidly advancing toward our goal of providing immunizations that protect infants, children and adults around the world from all causes of this deadly disease.

Based on the positive results from this and similar studies across other age groups, the Novartis MenB vaccine is potentially the first broad coverage meningitis B vaccine to advance to the final stage of clinical testing. The vaccine entered Phase III clinical trials in the first quarter of 2008. Novartis is currently the only company with vaccines against all five key disease-causing meningococcal serogroups (A, B, C, W-135, Y) in international Phase III trials.

The meningococcal B strain causes the majority of meningococcal infections in developed nations including Europe, Canada, Australia and the US. In these countries, serogroup B is responsible for 42 to 80 percent of meningococcal cases⁽²⁾. Worldwide incidence of serogroup B disease is estimated to be 20,000 to 80,000 cases per year⁽⁵⁾.

Novartis MenB vaccine study details⁽¹⁾

The Novartis MenB vaccine was administered to 150 healthy UK infants concomitantly with routine immunizations at 2, 4 and 6 months of age, along with a booster dose at 12 months of age. The vaccine's protective immune response was assessed by the percentage of subjects achieving hSBA titers $\geq 1:4$ using strains representing three major vaccine antigens. One month after the third dose, the percentages of subjects achieving a protective immune response were 89%, 96% and 85%. After the booster dose given at 12 months of age the percentages of subjects with a protective immune response were 100%, 98% and 93% and was indicative of an immune memory response. The hSBA titers were measured one month following the third and fourth doses. The hSBA assay measures the body's protective immune response based on the ability of antibodies to kill the bacteria. The vaccine was well tolerated.

Novartis has broad portfolio of meningitis vaccines

Two other presentations at ESPID detail other positive clinical trial results for vaccines for prevention of meningococcal disease from Novartis. Pooled data from Phase II studies involving 2,190 participants showed that Menveo[®] (MenACWY-CRM), the investigational vaccine for the four other common meningococcal serogroups, A, C, W-135 and Y, produced a strong protective immune response in individuals from two months to 17 years of age⁽⁶⁾. Results from another phase III study showed that Menveo can be safely given to adolescents at the same time as the commonly used diphtheria, tetanus and pertussis (whooping cough) (Tdap) vaccine⁽⁷⁾.

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Menveo has the potential to become the first meningococcal vaccine to protect people in age groups from infancy to adulthood against these four vaccine-preventable meningococcal serogroups. Regulatory marketing applications are anticipated in the EU and US later this year.

Novartis is a global leader in providing vaccines to protect against deadly meningococcal disease. In addition to developing Novartis MenB vaccine and Menveo, Novartis pioneered the development of meningococcal conjugate vaccines with Menjugate[®], a meningococcal serogroup C conjugate

vaccine approved outside the US since 2000 for use in individuals from two months of age through adulthood. More than 26 million doses of Menjugate have been distributed. Three million doses of MeNZB, a vaccine against a strain of meningococcus B specific to New Zealand, have been administered to help in successfully curbing a recent outbreak there.

About meningococcal disease, a leading cause of bacterial meningitis

Meningococcal disease, a contagious and potentially deadly infection caused by the bacterium *Neisseria meningitidis* (*N. meningitidis*), may occur suddenly in previously healthy individuals. It can manifest as bacterial meningitis – an infection of the membranes around the brain and spinal cord – or sepsis, a bloodstream infection. Each year, approximately 500,000 cases of meningococcal disease occur around the world, causing about 50,000 deaths⁽⁸⁾.

The symptoms – which can include sudden onset of fever, rash, headache, and stiff neck – can progress rapidly. There are effective treatments; however, the disease can be difficult to diagnose, can progress very quickly and is associated with high fatality even with appropriate treatment. Deaths can occur within 24 hours⁽⁹⁾, ⁽¹⁰⁾ of the onset of symptoms. Up to 10 percent of cases are fatal and up to 20 percent of survivors are left with permanent disability such as deafness, neurological damage or limb loss⁽⁵⁾.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, on track, promise, potentially, would, likelihood, likely, believed, commitment, goal, estimated, may, can, or similar expressions, or by express or implied disclosure regarding potential future regulatory filings or approvals for, or potential future sales of, Novartis MenB vaccine, Menveo or other related 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 Novartis MenB vaccine or Menveo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis MenB vaccine or Menveo or any other related vaccine currently in development by Novartis will be submitted or approved for any indications in any market. Nor can there be any guarantee that Novartis MenB vaccine, Menveo or any other related vaccine currently in development by Novartis, if approved, will achieve any particular levels of sales. In particular, management's expectations regarding Novartis MenB vaccine or 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 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 AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely 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

- (1) Miller E, Pollard A, Borrow R, et al. Safety and Immunogenicity of Novartis Meningococcal serogroup B vaccine after three doses administered in infancy. Presented at European Society for Paediatric Infectious Diseases (ESPID) annual meeting; May 14, 2008; Graz, Austria.
- (2) Australian Meningococcal Surveillance Programme 2005;CCDR 2007;CDC 2006; Chiavetta et al. 2007; Chiou et al. 2006; Ciccone et al. 2006; Coulson et al. 2007; EU-IBIS 2004; Instituto Nacional de Salud (Colombia) 2007; Martin et al. 2005; Nicolas et al. 2005; Takahashi et al. 2004 European Union Invasive Bacterial Infections Surveillance Network. www.euibis.org. Data on File/p4/table
- (3) Rosenstein NE, Perkins BA, Stephens DS, Popovic T, Hughes JM. Meningococcal disease. *N Engl J Med*. May 3 2001;344(18):1378-1388.
- (4) European Union Invasive Bacterial Infections Surveillance (EU-IBIS) Network. Invasive Neisseria meningitidis in Europe 2006. Health Protection Agency, London 2006. www.eubis.org.
- (5) World Health Organization. Initiative for Vaccine Research, Bacterial Infections. Neisseria meningitidis. Available at:
http://www.who.int/vaccine_research/diseases/soa_bacterial/en/index2.html
- (6) Black S, Dull P. MenACWY-CRM, a novel quadrivalent meningococcal conjugate vaccine, is well tolerated and immunogenic in infancy through to adolescence. Presented at European Society for Paediatric Infectious Diseases (ESPID) annual meeting; May 14, 2008; Graz, Austria .
- (7) Gasparini R, Conversano M, Bona G, et al. Immunogenicity and safety of MenACWY-CRM, a novel quadrivalent meningococcal conjugate vaccine, administered concomitantly with Tdap in healthy subjects 11-25 years-of-age. Presented at the European Society for Paediatric Infectious Diseases (ESPID) annual meeting; May 14, 2008; Graz, Austria
- (8) WHO Weekly Epidemiological Record. Meningococcal vaccines: polysaccharide and polysaccharide conjugate vaccines. 40(77); 329-340, 2002.

- (9) Bilukha O, Messonnier N, Fischer M. Use of meningococcal vaccines in the United States. *Pediatr Infect Dis J.* May 2007;26(5):371-376.
- (10) Thompson MJ, Ninis N, Perera R, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet.* Feb 4, 2006;367(9508):397-403.

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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: May 14, 2008

By: /s/ MALCOLM B. CHEETHAM

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