NOVARTIS AG
Form 6-K
October 26, 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 October 25, 2010**

**(Commission File No. 1-15024)**

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# Novartis AG

(Name of Registrant)

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Yes: o **No**: x

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**- Investor Relations Release -**

**Phase III data show that Novartis meningococcal vaccine Menveo® demonstrated robust immunogenicity in infants**

- *New pivotal phase III data show Menveo induced immune responses in a high percentage of infants against four important meningococcal disease-causing serogroups*(1)

- *The highest rates of meningococcal disease, a sudden, serious and often deadly disease, occur early in the first year of life*(2)

- *Menveo has the potential to be the first meningococcal quadrivalent conjugate vaccine that induces high levels of protective antibodies in infants vaccinated from 2 months of age*

**Basel, October 25, 2010** New Phase III data indicate that Menveo® (Meningococcal Group A, C, W135 and Y conjugate vaccine) demonstrated robust immunogenicity in infants potentially offering protection against four major serogroups of meningococcal disease(1), (3). These data were presented during an oral presentation at the 48th annual meeting of the Infectious Disease Society of America (IDSA) held in Vancouver, Canada.

This pivotal trial, including more than 4,500 infants worldwide, met its primary endpoints. Results show that a high percentage of infants vaccinated with four doses achieved robust immune responses against meningococcal serogroups A, C, W135 and Y(1). Menveo was generally well tolerated when given either alone or co-administered with other pediatric vaccines(1). Menveo has the potential to be the first meningococcal quadrivalent conjugate vaccine that induces high levels of protective antibodies against serogroups A, C, W135 and Y in infants vaccinated from 2 months of age. Infants under one year of age are at greatest risk for meningococcal disease and currently no broad-coverage vaccine is licensed for this population(2), (3).

In my practice I have seen the devastating effects of meningococcal disease in infants, said Stan Block, MD, FAAP, an investigator for the study. Meningococcal vaccines are being developed that can provide broad protection against the disease in this vulnerable population(2).

Menveo has the potential to fulfill an unmet medical need as a vaccine that can help protect people, from early infancy to adulthood, against four major causes of meningococcal disease (serogroups A, C, W135 and Y)(4), (5), a sudden, unpredictable and often life-threatening illness(2), (2). Together these four serogroups cause the majority of meningococcal disease cases in the United States (US), Africa, and the Middle East and are also present in Europe, Asia and Latin America(6), (7).

As the most vulnerable age group, infants should be directly protected from this unpredictable and devastating disease, said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. These data are another step in the significant progress Novartis is making toward our goal of protecting all age groups against meningococcal disease.

In the US, Novartis intends to submit a supplemental Biologics License Application (sBLA) based on these pivotal data to the US Food and Drug Administration (FDA) by year-end. If approved, Menveo will be the only meningococcal quadrivalent conjugate vaccine that could be administered to infants 2 months of age and older. This label claim extension will be also submitted in Europe and in other parts of the world.

**Menveo Clinical Trial Results and Design**

The Phase III, randomized, open-label, multi-center, parallel-group study is the first to evaluate and present results for a meningococcal quadrivalent conjugate vaccine in infants. The study involved 4,545 healthy infants in trial sites throughout the US and Latin America. Only data from the US trial sites were presented at IDSA. Infants were randomized 2:1 to receive routine infant vaccinations (DTaP, IPV, HBV, Hib, pneumococcal) alone or together with Menveo at 2, 4, 6 and 12 months of age. The primary objectives of the study were to assess the safety and tolerability of four doses of Menveo when given alone or co-administered with routine infant vaccines and, in a subset, to assess the immune response to the vaccine(1).

The percentage of infants who achieved a protective immune response was 67 percent for serogroup A, 97 percent for serogroup C, and 96 percent for serogroups W135 and Y when measured at 7 months of age, one month after the third dose. One month after the fourth dose at 12 months of age, the percentages were 94 percent for serogroup A, 98 percent for serogroup C, and 100 percent for serogroups W135 and Y. The immune response was measured by the percentage of participants achieving serum bactericidal antibody titers $\geq$1:8, using human complement (hSBA). In addition, responses to routine infant vaccine antigens, when co-administered with Menveo, were generally similar, except for a slightly lower immune response to pneumococcal serotype 6B after the infant series(1).

When given alone, Menveo was well tolerated, with a reactogenicity and safety profile similar to routine infant vaccines. Co-administration of Menveo with routine infant immunizations neither resulted in increased frequency nor severity of systemic reactions or other safety events. The most common side effects in both groups were sleepiness, irritability, persistent crying, changed eating habits, rash, and gastrointestinal events. Rates of fever $\geq$38° C were similar in both groups with the majority of cases resolving within 24-48 hours. Incidence of serious adverse events was not different between the groups.

**About Meningococcal disease**

Meningococcal disease is a leading cause of bacterial meningitis an infection of the membrane around the brain and spine and sepsis a bloodstream infection(3), (8). Survivors of meningococcal disease may experience side effects, called sequelae, such as brain damage, learning disabilities, hearing loss and limb loss(2). Five main serogroups of meningococcal bacteria (A, B, C, W135 and Y) cause the majority of all cases around the world(2). Infants are at the greatest risk of developing meningococcal disease and represent the greatest unmet need in terms of prevention(2), (4). According to the US Centers for Disease Control and Prevention, there are two incidence peaks of meningococcal disease, with the highest rates in the first year of life (peak incidence at 4 to 5 months of age) and the other in adolescence(4). Up to 10 percent of children younger than 12 months of age, who contract meningococcal disease, die (9). Globally, there are more than 500,000 cases of meningococcal disease each year, leading to more than 50,000 deaths(3).

**About Menveo**

Menveo is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W135 and Y in individuals 11-55 years of age in the US, Chile, Argentina, and individuals 11 years of age and older in the European Union, Peru, Indonesia, Malaysia, Australia, Canada, and Pakistan. Menveo does not prevent *N. meningitidis* serogroup B infections(10).

Menveo is also being evaluated for safety and immunogenicity using various schedules in 24 completed and ongoing studies, 16 of which are in infant and toddlers, and eight in adolescents and adults. Menveo has been administered to more than 18,500 clinical subjects across all age groups worldwide.

Novartis plans to submit additional data to the European Medicines Agency to support the use of Menveo in infants 2 months through 2 years of age, as well as in children 2 to 10 years of age. An sBLA for the use of Menveo in children 2 to 10 years of age is currently under review by the FDA.

**About Novartis Vaccines global meningococcal franchise**

Novartis Vaccines is a global leader in providing vaccines to help protect against potentially 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 the investigational Multicomponent Meningococcal Serogroup B Vaccine (4CMenB), which has the potential to provide protection against a range of serogroup B strains. Menveo vaccine is based on the same proprietary technology Novartis Vaccines pioneered to produce Menjugate®, a meningococcal serogroup C conjugate vaccine approved in many countries outside the US since 2000. The Company has already distributed more than 45 million doses of Menjugate around the world and produced MenZB®, a vaccine against a strain of meningococcus B specific to an outbreak in New Zealand.

**Important Safety Information**

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 potential, potentially, can, should, intends, will, could, plans, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo, potential future approvals of the 4CMenB vaccine, 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 4CMenB will be submitted or approved for sale in any market. Neither can there be any guarantee that these vaccines will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these 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 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

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**References**

(1) Klein NP, Gill CJ, Bedell L, Karsten A, Dull PM. Pivotal safety and immunogenicity of an investigational quadrivalent meningococcal vaccine (MenACWY-CRM; Menveo®) in 4545 infants. Presented at the 48th Annual Meeting of the Infectious Diseases Society of America in Vancouver, British Columbia, Canada on October 21-24, 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 October 12, 2010.

(3) 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 October 12, 2010.

(4) Centers for Disease Control and Prevention. Recommended Immunization Schedule for Persons Aged 0 Through 6 Years United States. Available at: http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_0-6yrs-schedule-pr.pdf. Accessed on October 12, 2010.

(5) Centers for Disease Control and Prevention. Recommended Immunization Schedule for Persons Aged 7 Through 18 Years United States. Available at http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2010/10_7-18yrs-schedule-pr.pdf. Accessed on October 12, 2010.

(6) Harrison LH, Trotter CL, Ramsay ME. Global epidemiology of meningococcal disease. Vaccine. June 24, 2009; 27 Suppl 2:B51-63. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19477562. Accessed on October 12, 2010.

(7) Sáfadi MA, Cintra OA. Epidemiology of meningococcal disease in Latin America: current situation and opportunities for prevention. Neurological Research. April 2010; 32(3): 263-71. Available at: http://www.ncbi.nlm.nih.gov/pubmed/20406604. Accessed on October 12, 2010.

(8) Centers for Disease Control and Prevention. Meningitis: Questions & Answers. June 2009 update. Available at: http://www.cdc.gov/meningitis/about/faq.html. Accessed on October 12, 2010.

(9) 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.

(10) Menveo® Highlights of Prescribing Information. February 2010.

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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: October 25, 2010

By: /s/ MALCOLM B. CHEETHAM

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