

NOVARTIS AG  
Form 6-K  
November 04, 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 November 4, 2010**

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

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**Novartis AG**

(Name of Registrant)

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(Address of Principal Executive Offices)

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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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**Novartis International AG**

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**- Investor Relations Release -**

**New data show potential for Novartis Meningitis B vaccine (4CMenB) candidate to cover majority of diverse meningococcal serogroup B strains**

- *Data show that antibodies induced by Novartis 4CMenB candidate killed 85 percent of a large collection of MenB strains in adults and 74 percent in infants(1), who are at highest risk for meningococcal disease(2)*
- *Findings highlight the benefit of a multi-component MenB vaccine to provide broad coverage against diverse strains(1)*
- *Innovative Meningococcal Antigen Typing System (MATS) has been developed to predict strain coverage and evolution across the globe*

**Basel, November 4, 2010** New data demonstrated that antibodies induced by Novartis Vaccines investigational, four component, Meningococcal Serogroup B Vaccine (4CMenB) killed the majority of a collection of geographically and genetically diverse meningococcal serogroup B (MenB) strains. The strain coverage research findings were recently published in the *Proceedings of the National Academy of Sciences*.

To define the potential coverage of 4CMenB against circulating MenB strains, the research investigators examined the characteristics of a collection of 124 MenB strains using pooled sera from immunized adults, and 57 strains using pooled sera from immunized infants(1). The strains were selected to represent a wide range of variability of antigens but were not intended to represent any specific regional epidemiologic sample of MenB strains. The data demonstrated that 85 percent of the tested strains were killed by pooled sera of adults vaccinated with 4CMenB, as measured by serum bactericidal assay (SBA)(1). SBA is an established and validated correlate of protection. Additionally, the vaccine performed well in infants; even though infant immune systems are still maturing(3), 74 percent of strains were killed using pooled sera from infants vaccinated with 4CMenB(1). Infants are most at risk of MenB disease and their protection presents the greatest unmet need(2).

In addition to the vaccine coverage results, a subsequent analysis of a new predictive model, Meningococcal Antigen Typing System (MATS), against the tested MenB strains, supported the potential benefits of a multi-component vaccine. When MATS detected that three vaccine antigens were sufficiently present on any MenB strain, 100 percent of the time these strains were killed by pooled sera from immunized

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adults(1). In addition, when one or two antigens were detected to be sufficiently present on any MenB strain, 85 and 94 percent of the time, respectively, they were killed(1).

These important findings support our innovative approach using multiple novel components in a single vaccine to provide broad coverage against the deadly and unpredictable MenB disease, said Andrin Oswald, Head of Novartis Vaccines and Diagnostics Division. Novartis is committed

to developing a MenB vaccine that protects all age groups who are at highest risk of contracting often deadly MenB disease, especially infants and young children(2) .

MATS is a new, simple and reproducible assay that correlates with SBA to overcome the challenge of traditional SBA testing on large collections of strains. The immense diversity and number of circulating MenB strains around the world(2) and the limited infant serum volume derived from clinical trials makes traditional testing difficult and cannot be made a routine procedure(1). Novartis Vaccines, in collaboration with Novartis Diagnostics, developed MATS as a scientific model to predict whether MenB strains are potentially covered by the vaccine.

The MATS method allows simple and rapid prediction of potential vaccine coverage in different geographic regions and monitoring of strain evolution. Its results alone are not intended to demonstrate, and do not imply, clinical effectiveness.

The MATS model is a milestone in meningococcal serogroup B vaccine development, said Joel Ward MD, Professor of Pediatrics at the Center for Vaccine Research, School of Medicine, University of California Los Angeles. Given the geographic diversity of MenB and the potential for mutation, it was previously considered impossible to evaluate immune responses to the many circulating strains that can cause deadly disease(2). MATS has the potential to be used for vaccines against meningococcal diseases and for vaccines against other bacteria as well.

Novartis is providing the MATS assay platform to national and regional reference laboratories around the world. These institutions are analyzing their local or regional circulating strains to predict the potential coverage of 4CMenB in their territories. National coverage data on more than 1,500 MenB strains are expected to be available by the middle of 2011.

## **Research Design**

The research included 124 meningococcal serogroup B strains that were obtained from meningococcal reference laboratories in the UK, France, Germany, Italy, Norway, New Zealand, Australia and the US(1). Healthy human adult volunteers were immunized with 4CMenB and sera were collected(1) and pooled(1). A prioritized subset of 57 strains was analyzed with serum from infants immunized at 2, 4, 6 and 12 months of age(1). Since less serum was available from infants, fewer strains were tested in this age group(1).

MATS accurately predicted the percentage of epidemiologically diverse, disease-causing MenB strains that 4CMenB would cover (or kill in SBA) in adults and infants by evaluating their antigen detection level and cross-protective immune response(1). To establish the MATS method, results were compared with killing of MenB, determined by SBA in human complement (hSBA), the most direct and established approach to measure vaccine's protective immune response, using pooled sera from adults and infants vaccinated with 4CMenB(1).

## **About 4CMenB**

The Novartis 4CMenB vaccine was developed using a pioneering approach known as reverse vaccinology. In contrast to conventional methods of developing vaccines, reverse vaccinology decodes the genetic makeup (genome sequence) of MenB and selects those proteins that are most likely to be protective vaccine candidates(4). 4CMenB targets multiple components and is designed to provide an optimal immune response

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against the majority of MenB strains, while at the same time addressing the constantly changing nature of the bacteria.

4CMenB is the only candidate MenB vaccine currently in Phase III testing. Comprehensive data from more than 7,500 infant and adolescent/adult subjects is expected to be the basis for the planned filing in the EU by year end.

## About Meningococcal Disease

Invasive meningococcal disease is a sudden, aggressive illness that can lead to death within 24-48 hours of the first symptoms<sup>(5)</sup>, <sup>(6)</sup>. The disease poses a significant burden to people around the world, especially infants, who are at highest risk for infection<sup>(2)</sup>, <sup>(7)</sup>. MenB causes up to 80 percent of meningococcal disease cases in Europe<sup>(8)</sup>, up to 55 percent of cases in Canada<sup>(9)</sup> and 30 percent of cases in the US<sup>(8)</sup>. MenB strains circulate worldwide, can mutate and may result in long-term regional outbreaks<sup>(2)</sup>.

Meningococcal disease caused by groups A, C, W135 and Y is vaccine-preventable; however, MenB remains an unmet public health need as the most common cause of bacterial meningitis for which there is no licensed broad-spectrum vaccine<sup>(7)</sup>. Global incidence of MenB infection is estimated to be between 20,000 and 80,000 cases per year, with a 10 percent fatality rate<sup>(10)</sup>.

Meningococcal disease is a leading cause of bacterial meningitis – an infection of the membrane around the brain and spine – and sepsis – a bloodstream infection<sup>(11)</sup>, <sup>(12)</sup>, <sup>(13)</sup>. Survivors may experience side effects, called sequelae, such as brain damage, learning disabilities, hearing loss and limb loss<sup>(13)</sup>.

## 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 the Men ACWY conjugate vaccine, Menveo®, Novartis Vaccines is developing an investigational, four component, 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, and of which more than 45 million doses have been distributed around the world<sup>(14)</sup>. Novartis Vaccines also developed and produced MenZB®, a vaccine targeting specifically one strain of meningococcus B causing an outbreak in New Zealand.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, risk, predict, committed, prediction, expected, planned, can, may, potentially, developing, or similar expressions, or by express or implied discussions regarding marketing approvals for 4CMenB, or the timing of such approvals, or regarding potential future revenues from 4CMenB. 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 with 4CMenB to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that 4CMenB will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that 4CMenB will achieve any particular levels of revenue in the future. In particular, management's expectations regarding 4CMenB 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; government, industry and general public pricing pressures; competition in general; 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 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>.

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

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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: November 4, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting