

NOVARTIS AG  
Form 6-K  
December 23, 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 December 23, 2010

(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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Form 20-F:  Form 40-F:

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Yes:  No:

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**- Investor Relations Release -**

**Novartis submits Bexsero®, a multi-component meningococcal B vaccine, for regulatory review in Europe**

- *Bexsero is the first vaccine with the potential to offer broad coverage against a large number of circulating, deadly disease-causing MenB strains(1),(2)*
- *Data from more than 7,500 subjects support use of the vaccine in infants from two months of age and older, adolescents, and adults(3),(4),(5)*

**Basel, December 23, 2010** Novartis announced today that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Bexsero® (Multi-Component Meningococcal B Vaccine; formerly known as 4CMenB). Upon approval, Bexsero will be the first broad-coverage vaccine licensed for use against disease caused by meningococcal serogroup B bacteria (MenB) in all European Union (EU) and European Economic Area (EEA) countries(1), (2). Submission is supported by comprehensive clinical and epidemiological data which characterize the safety and immunogenicity profile, and the predicted coverage of Bexsero(3), (4), (5).

The Bexsero submission in the EU is an important milestone toward achieving the world's first broad-coverage MenB vaccine through our unique multi-component approach(1), (2), said Andrin Oswald, Head of Novartis Vaccines and Diagnostics Division. Meningococcal disease is sudden and aggressive, leaving little time for treatment(6), (7). Proactive vaccination of individuals has been shown to offer the best protection against fatal infectious diseases. Novartis is committed to providing vaccines to protect people of all ages, including infants, and against all causes, of meningococcal disease.

The tremendous diversity of MenB strains around the world has been one of the main challenges to developing an effective broad-coverage MenB vaccine(13). The four distinct antigen components of Novartis' Bexsero vaccine were selected because they are important for the bacteria's survival, function or ability to cause infection, and can be found in the majority of MenB strains circulating worldwide(1), (14), (15). Data predict that the majority of strains would be covered by more than one of the Bexsero vaccine antigens, preventing disease caused by current MenB strains and by eventual genetic strain shifts(5).

Coverage data have been generated to predict the ability of the vaccine to protect infants vaccinated at 2, 4, 6 and 12 months of age against the disease-causing MenB strains circulating in their local environments(5). Preliminary data show that Bexsero covers potentially 77 percent (95% confidence limits from 66-91%) of more than 800 genetically diverse disease-causing MenB strains isolated in Europe in recent years(5). The strong coverage estimates of Bexsero highlight the unique benefits of the multi-component approach. Analysis of additional strains is currently ongoing and expected to be shared in 2011.



Completed clinical trials involved more than 7,500 infants, adolescents and adults. In infants, studies show that Bexsero could be either co-administered with other routine vaccines or as part of a flexible vaccination schedule.

The EU regulatory submission for Bexsero is planned to form the basis for further submissions. Novartis has prioritized future submissions where the potential public health impact is greatest, including countries in Asia, Latin America and North America.

### **About Bexsero**

The Novartis Bexsero 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 broadly-effective vaccine candidates(16). Bexsero contains multiple components, which independently are highly immunogenic and, taken together, have the potential to protect against a broad range of disease-causing strains(1), (14), (15).

### **About Meningococcal Disease**

Invasive meningococcal disease is a sudden, aggressive illness that can lead to death within 24-48 hours of the first symptoms(6), (7). It is a leading cause of bacterial meningitis – an infection of the membrane around the brain and spine(8) – and sepsis – a bloodstream infection(7), (12). Survivors may experience side effects, called sequelae, such as brain damage, learning disabilities, hearing loss, and limb amputations(12).

Licensed vaccines are available to protect against meningococcal disease caused by serogroups A, C, W135 and Y(8); however, meningococcal disease caused by serogroup B has posed a significant burden to people around the world, especially infants, who are at highest risk for infection(10), (11). Global incidence of MenB infection is estimated to be between 20,000 and 80,000 cases per year, with a 10 percent fatality rate(17). In Europe, MenB causes up to 80 percent of meningococcal disease cases(9). MenB strains circulate worldwide, can mutate and may also result in long-term regional outbreaks over and above the ongoing baseline threat. MenB has caused such outbreaks of disease around the world, including in New Zealand, the United Kingdom, and France(1).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, would, predicted, committed, will, predict, potentially, expected, planned, may, can, or similar expressions, or by express or implied discussions regarding potential approvals for Bexsero, potential strain coverage for Bexsero, potential future regulatory submissions to market Bexsero in additional countries, or regarding potential future revenues from Bexsero. 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 Bexsero to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Bexsero will be approved for sale in any market. Nor can there be any guarantee that Bexsero will achieve any particular levels of strain coverage. Neither can there be any guarantee that Bexsero will be submitted for marketing approval in any additional countries, including the United States. Nor can there be any guarantee that Bexsero will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Bexsero 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; unexpected strain coverage analysis results, or unexpected efficacy issues; 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 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: December 23, 2010

By: /s/ MALCOLM B. CHEETHAM

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