

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)

---

## Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(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:

Edgar Filing: NOVARTIS AG - Form 6-K

Form 20-F:  Form 40-F:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes:  No:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  No:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes:  No:

---

**Novartis International AG**  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

**- 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>.

---

## References

- (1) Perrett KP, Pollard AJ. Towards an improved serogroup B *Neisseria meningitidis* vaccine. *Expert Opin Biol Ther.* 2005; 5:1611-1625.
- (2) Donnelly, J et al. Qualitative and quantitative assessment of meningococcal antigens to evaluate the potential strain coverage of protein-based vaccines. *Proceedings of the National Academy of Sciences.* November 2010. Available at: <http://www.pnas.org/content/early/2010/10/19/1013758107.full.pdf>. Accessed on December 8, 2010.
- (3) Esposito, S et al., Tolerability of a three-dose schedule of an investigational, multicomponent meningococcal serogroup B vaccine and routine infant vaccines in a lot consistency trial, presented at the 17th International Pathogenic *Neisseria* Conference, September 11-16, 2010, Banff, Canada.
- (4) Vesikari, T et al., Immunogenicity of an investigational multicomponent meningococcal serogroup B vaccine in healthy infants at 2, 4 and 6 months of age, presented at the 17th International Pathogenic *Neisseria* Conference, September 11-16, 2010, Banff, Canada.
- (5) Novartis Data on File. (Draft summary of product characteristics for Bexsero)
- (6) Centers for Disease Control and Prevention. Meningitis: Diagnosis. June 2009 update. Available at: <http://www.cdc.gov/meningitis/about/diagnosis.html>. Accessed on December 9, 2010.
- (7) World Health Organization. Meningococcal meningitis fact sheet. Available at: <http://www.who.int/mediacentre/factsheets/fs141/en>. Accessed on December 9, 2010.
- (8) 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](http://www.who.int/immunization/wer7740meningococcal_Oct02_position_paper.pdf). Accessed on December 9, 2010.
- (9) Pizza M, Scarlato V, Masignani V, et al. Identification of vaccine candidates against serogroup B meningococcus by whole-genome sequencing. *Science.* 2000; 287:1816-1820.
- (10) 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](http://www.nfid.org/pdf/meningitis/FINALChanging_Epidemiology_of_Meningococcal_Disease.pdf). Accessed on December 9, 2010.
- (11) Pollard, A. J. and Maiden, C.J. (Eds.) (2001). *Meningococcal disease: Methods and protocols.* Totowa, NJ: Humana Press, Inc.
- (12)

## Edgar Filing: NOVARTIS AG - Form 6-K

Centers for Disease Control and Prevention. Epidemiology and prevention of vaccine-preventable diseases. Atkinson W, Wolfe S, Hamborsky J, McIntyre L, eds. 11th ed. Washington DC: Public Health Foundation, 2009.

- (13) Harrison LH. Prospects for vaccine prevention of meningococcal infection. *Clin Microbiol Rev.* 2006; 19(1):142-1643. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1360272/>. Accessed on December 9, 2010.



- (14) Comanducci M, Bambini S, Brunelli B, et al. NadA, a novel vaccine candidate of Neisseria meningitidis. J Exp Med. 2002;195(11):1445-1454.
- (15) Lucidarme J, Comanducci M, Findlow J, et al. Characterization of fHbp, nhba (gna2132), nadA, porA, sequence type (ST), and genomic presence of IS1301 in group B meningococcal ST269 clonal complex isolates from England and Wales. J Clin Microbiol. 2009;47(11):3577-3585.
- (16) Rappuoli, R. Reverse vaccinology, a genome-based approach to vaccine development. Vaccine. 2001; 19: 2688-2691.
- (17) 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](http://www.who.int/vaccine_research/diseases/soa_bacterial/en/index2.html). Accessed on December 9, 2010.

###

### Novartis Media Relations

**Central media line :** +41 61 324 2200

**Eric Althoff**

Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 593 4202 (mobile)  
eric.althoff@novartis.com

**Natacha Gassenbach**

Novartis Vaccines and Diagnostics  
+1 617 871 8341 (direct)  
+1 617 852 8609 (mobile)  
natacha.gassenbach@novartis.com

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

For Novartis multimedia content, please visit [www.thenewsmarket.com/Novartis](http://www.thenewsmarket.com/Novartis)  
For questions about the site or required registration, please contact: [journalisthelp@thenewsmarket.com](mailto:journalisthelp@thenewsmarket.com).

### Novartis Investor Relations

**Central phone:**

Susanne Schaffert +41 61 324 7944  
Pierre-Michel Bringer +41 61 324 3769  
Thomas Hungerbuehler +41 61 324 1065  
Isabella Zinck +41 61 324 8425  
+41 61 324 7188

**North America:**

Richard Jarvis +1 212 830 2433  
Jill Pozarek +1 212 830 2445  
Edwin Valeriano +1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**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

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