

NOVARTIS AG  
Form 6-K  
November 16, 2012

# 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 16, 2012**

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

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(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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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis receives positive CHMP opinion for Bexsero®, a groundbreaking vaccine to help prevent devastating MenB infections, the leading cause of meningitis in Europe**

- *Meningococcal serogroup B (MenB) disease is easily misdiagnosed, can kill within 24 hours and may cause serious, life-long disabilities(1),(2)*
- *Upon approval, Bexsero will be the first and only broad coverage MenB vaccine to help protect all age groups, including infants*
- *Anticipated approval of Bexsero highlights Novartis leadership position in global fight against meningococcal disease*

**Basel, November 16, 2012** Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Bexsero® (Meningococcal Group B Vaccine [rDNA, component, adsorbed]) for use in individuals from 2 months of age and older.(3) Upon regulatory approval, Bexsero will be the first licensed broad coverage vaccine that can help protect all age groups against MenB disease,(4) including infants, the age group at the greatest risk of infection.(5)

We are proud of the major advance that Bexsero represents within the field of vaccine development against what up until now has been a very challenging disease target, said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. For over two decades, our researchers and clinicians have been dedicated to finding a solution to prevent MenB disease. Our steadfast determination has been inspired by the testimonies from survivors and families who have lost loved ones to this disease.

Currently available vaccines do not offer broad protection against MenB, which accounts for up to 90% of all meningococcal disease cases in some European countries.(6) MenB disease is easily misdiagnosed, can kill within 24 hours and may cause serious, life-long disabilities.(1),(2) About 1 in 10 of those who contract the disease dies despite appropriate treatment.(2) Up to one in five survivors suffers from devastating, life-long disabilities such as brain damage, hearing impairment or limb loss.(5) The highest rates of MenB disease occur in the first year of life, peaking by 7 months of age.(7)

MenB disease is a major cause of meningitis and septicemia in children, and its ability to cause a rapidly progressive, devastating illness makes it one of the infections most feared by both parents and pediatricians, said Dr Matthew Snape, Consultant in Pediatrics and Vaccinology at the

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Oxford Vaccine Group, University of Oxford. A vaccine that is able to reduce the incidence of this disease would be a major advance towards the prevention of childhood meningitis.

The European Commission generally follows the recommendations of the CHMP and delivers its final decision within three months, which will be applicable to all European Union (EU) and European Economic Area (EEA) countries. Upon approval, each member state will evaluate Bexsero reimbursement schemes and determine the potential

inclusion of the vaccine into National Immunization Programs. Novartis is committed to making Bexsero available as soon as possible and is already engaging with governments interested in the early adoption of the vaccine.

The tolerability profile and immunogenicity of Bexsero has been established through a comprehensive clinical program including data from large Phase II/III clinical trials involving almost 8,000 infants, children, adolescents and adults.(8),(9),(10),(11),(12),(13) Starting from two months of age, Bexsero offers several immunization schedule options that can fit with routine vaccination visits.

We welcome this news, which is immensely significant for parents and doctors. For the first time in the fight against meningococcal disease, we have in sight a potential solution in protecting against MenB disease, said Bruce Langoulant, President and Member, Governing Council of Confederation of Meningitis Organisations (CoMO), and father of a meningitis survivor. Many of our members and supporters have been personally impacted by meningitis and have watched as loved ones suffered the devastating effects of this disease.

Bexsero is the result of more than 20 years of pioneering vaccine research.(14) MenB has been a particularly challenging target because the outer coating of the bacteria is not well recognized as an antigen by the immune system, making it especially difficult to develop a broadly effective vaccine until recent scientific developments.(15) Bexsero was developed using an award-winning scientific approach that involved decoding the genetic makeup (genome sequence) of MenB.(14),(15) This innovative approach provides the foundation for a new generation of vaccines that can help prevent other diseases with a significant diversity of disease-causing strains.

Following the approval of Menveo® in 2010, the anticipated approval of the groundbreaking vaccine Bexsero underscores the unique leadership position of Novartis in the global fight against devastating meningococcal disease. Together, the two vaccines help to protect against all five main serogroups of meningococcal bacteria (A, B, C, W-135 and Y) that cause the majority of cases around the world.(16)

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as anticipated, positive opinion, can, may, will, generally follows, recommendations, prospect, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Bexsero, or the timing of any such approvals, 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, or at any particular time. 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; government, industry and general public pricing pressures; unexpected manufacturing issues; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 127,000 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 16, 2012

By: /s/ MALCOLM B. CHEETHAM

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