NOVARTIS AG
Form 6-K
January 31, 2011

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 January 31, 2011

(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:

Form 20-F: x Form 40-F: o

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: o **No**: x

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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: o **No**: x

Novartis International AG

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- Investor Relations Release -

FDA approves the Novartis quadrivalent meningococcal conjugate vaccine, Menveo®, for use in children from 2 years of age

- *Expanded age indication of Menveo offers new option to help protect young children from 2 to 10 years of age against potentially devastating meningococcal disease(1)*

- *Novartis to resubmit Menveo infant indication within a few months*

Basel, January 31, 2011 Novartis announced today that it received approval from the US Food and Drug Administration (FDA) for the use of Menveo® (Meningococcal [Groups A, C, Y and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135 in individuals 2 to 10 years of age(1). Menveo received initial FDA approval in 2010 for use in adolescents and adults from 11 to 55 years of age(1).

The FDA approval of Menveo for use in children 2 to 10 years of age is based on Phase III trial data involving 5,297 participants in that age group. In the pivotal trial, the safety and immunogenicity of Menveo against each of the four serogroups were compared with those of the other currently US-licensed ACW-135Y meningococcal conjugate vaccine(1). Novartis also agreed to conduct three post marketing studies.

Separately, Novartis received a Refuse To File (RTF) letter from the FDA regarding the Company s supplemental Biologics License Application (sBLA) for the use of Menveo in infants from 2 to 12 months. The sBLA had been submitted to the FDA in November 2010. Novartis plans to resubmit a sBLA in 2011 for the expanded use of Menveo in infants and toddlers from 2 months to 2 years old.

The approval of Menveo for the use in children 2-10 years of age is another important step towards our goal to protect people of all ages against this devastating disease, said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. The response from the FDA on our Menveo infant file is disappointing. We believe that concerns raised are of procedural nature and plan to resubmit the sBLA within the next few months. This will also provide us with an opportunity to supplement the file with additional clinical data that support expanded use of Menveo in infants and toddlers from 2 months to 2 years old.

About Menveo

As of January 2011, Menveo is registered in more than 40 countries for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y in people from 11 years of age. Menveo has been administered to more than 18,500 participants in clinical trials across all age groups worldwide, and studies are ongoing in infants, toddlers, adolescents and adults(2). Menveo received initial FDA licensure in May 2010 for use in adolescents and adults (11 to 55 years of age)(1). Pivotal phase III data presented in October 2010 at the 48th Annual Meeting of the Infectious Diseases Society of America (IDSA) showed that Menveo induced immune responses in a high percentage of infants against four important meningococcal disease-causing serogroups (A, C, Y and W-135)(2).

In the EU, Menveo is known as Meningococcal Group A, C, W135 and Y Conjugate Vaccine. Novartis Vaccines plans to submit additional data to the European Medicines Agency to support the use of Menveo in infants and children 0 to 10 years of age in the first half of 2011. The label extension for use in children 2 to 10 years of age has already been submitted in Canada(2).

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 potentially, plans, goal, plan, can, potential, or similar expressions, or by express or implied discussions regarding potential submissions, resubmissions or approvals for new indications or labeling for Menveo, or the timing of any such submissions, resubmissions or approvals, or regarding potential future revenues from Menveo. 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 Menveo 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 submitted, resubmitted or approved for any additional indications or labeling in any market, or that any such submissions, resubmissions or approvals will occur at any particular time. Nor can there be any guarantee that Menveo will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Menveo could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including any unexpected inability to satisfy any conditions imposed by the government with respect to the resubmission of the infant indication in the US; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; 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; 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 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon 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) Novartis. Menveo® Full Prescribing Information. January 2011.

(2) Novartis Data on File.

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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: January 31, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting