NOVARTIS AG
Form 6-K
February 13, 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 February 13, 2012

(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

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: o **No**: x

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

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

FDA requests additional data on Novartis quadrivalent meningococcal conjugate vaccine, Menveo®, for expanded use in infants and toddlers

- *Agency issues Complete Response letter requesting more information to support approval*

Basel, February 13, 2012 Novartis has received a Complete Response letter from the US Food and Drug Administration (FDA) on its application for the expanded use of Menveo® (Meningococcal [Groups A, C, Y and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) in infants and toddlers from 2 months of age. Menveo is already approved for use in individuals 2 to 55 years of age in the US.

Novartis submitted the supplemental Biologics License Application (sBLA) for Menveo to the FDA in April 2011. The Complete Response letter indicates the FDA has completed the current review cycle and requests answers to additional questions prior to proceeding with further review of the sBLA. Novartis will work with the FDA to address these questions.

About Menveo

As of February 2012, Menveo is registered in more than 50 countries for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y. Menveo received the FDA approval for use in adolescents and adults (11 to 55 years of age) in February 2010 and approval for use in children 2 to 10 years of age in January 2011. Since launch, more than 3 million doses of Menveo have been distributed worldwide. Studies are ongoing in infants, toddlers, adolescents and adults.

Important Safety Information

Menveo is contraindicated in individuals who have experienced a severe allergic reaction after a previous dose of Menveo, any component of this vaccine, or any other CRM197, diphtheria toxoid or meningococcal-containing vaccine. Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur follow administration of Menveo.

Those vaccinated may develop syncope, sometimes resulting in falling with injury associated with seizure-like movements. Observation for 15 minutes after vaccination is recommended. Patients who are immunocompromised or receiving immunosuppressive therapy may have an inadequate response to vaccination.

Following vaccination with another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine, an evaluation of postmarketing adverse events suggested a potential for an increased risk of Guillain-Barré syndrome (GBS). Data are not available to evaluate the potential risk of GBS following administration of Menveo.

In clinical trials, the most frequently occurring adverse events in subjects 11 to 55 years of age who received Menveo were pain at the injection site, headache, myalgia, malaise, and nausea. The most frequently occurring adverse events in subjects 2-10 years of age

who received Menveo were pain at the injection site, erythema, irritability, induration, sleepiness, malaise, and headache. Safety has not been established in pregnant women. Vaccination with Menveo may not protect all individuals.

Before administering Menveo, please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Menveo 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 approved for any additional indications or labeling in any market or regarding the timing of any such approvals. 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; 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 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 124,000 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: February 13, 2012

By: /s/ MALCOLM B. CHEETHAM

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