

NOVARTIS AG  
Form 6-K  
November 09, 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 9, 2012**

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

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(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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**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:**

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

**Italian authorities lift precautionary hold on Novartis seasonal influenza vaccines**

- *Safety and efficacy of Agrippal® and Flud® reaffirmed; over one million people vaccinated this season with no unexpected adverse events reported to date*
- *Temporary holds already lifted in Canada and Switzerland(1),(2); decision from Italy to serve as reference for other EU countries*
- *Distribution to resume immediately to support vaccination against seasonal influenza, which leads to 250,000 to 500,000 deaths worldwide each year(3)*

**Basel, November 9, 2012** The Italian Medicines Agency (AIFA) announced today that the temporary halt on the use of Agrippal® and Flud® vaccines in Italy has been lifted. This follows additional information provided by the company and AIFA's independent assessment, which reaffirm the vaccines' safety and efficacy. For the 2012-2013 influenza season, more than one million doses have been administered with no unexpected adverse events reported to date.

Distribution already resumed for Canada and Switzerland on October 31, 2012(1),(2), as well as Singapore on November 2, 2012. Within the European Union (EU), Italy is the regulatory reference country for Agrippal and Flud. Novartis will continue to work with other countries to lift remaining precautionary measures and resume supply as soon as possible.

Novartis welcomes this positive development with the Italian authorities. Patient safety is our highest priority and we have always remained confident in the quality of our vaccines, said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. The safety and efficacy of Agrippal and Flud are supported by extensive clinical and surveillance data, including more than one million doses administered this season.

Influenza is a serious public health concern that causes severe illnesses and deaths, particularly in young children and the elderly, said Alberto Mantovani, MD, Scientific Director, Istituto Clinico Humanitas, Milan and Professor of Pathology, Università degli Studi di Milano. It is critical that the vaccination campaign can proceed with confidence in the safety and efficacy of the vaccines, and people get vaccinated to protect themselves and their loved ones.

Italian authorities halted the use of Agrippal and Flud vaccines on October 24, 2012, following the company's report of higher than usual levels of protein aggregates observed in one batch of seasonal influenza vaccine which was not released for use. This led to similar actions in other countries. These aggregates are formed by proteins essential to the vaccine, can naturally occur in very small quantities, and typically dissolve when shaken.

According to the World Health Organization (WHO), no other public health intervention, except the provision of clean drinking water, has done more to reduce the global burden

of disease than vaccination(4). It recommends annual seasonal influenza vaccination for the elderly, people with chronic medical conditions and other vulnerable groups, such as pregnant women, health care workers and those with essential functions in society, as well as children from ages 6 months to 2 years(3).

For more information, visit [www.novartisvaccines.com/fluinfor](http://www.novartisvaccines.com/fluinfor).

*Agrippal and Flud are not available in the United States of America and are marketed in Germany under the trade name Begripal®, in Italy additionally under the trade names Influpozzi sub unità® and Influpozzi adiuvato®, and in Spain under the trade name Chiromas®.*

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to serve, to resume, will, or similar expressions, or by express or implied discussions regarding the potential resumption of Agrippal and Flud distribution in other countries, or the timing of any such potential resumption, or regarding the potential financial impact of the suspensions of distribution of Agrippal and Flud. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the distribution of Agrippal and Flud will be resumed in the countries where its distribution remains suspended, or that any such resumption will take place at any particular time. Nor can there be any guarantee as to the potential financial impact on Novartis resulting from the suspensions. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing issues; 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 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 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 126,000 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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#### **References**

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(1) Health Canada. Voluntary Suspension of Flu Vaccines (Agriflu and Fluad) Lifted. October 31, 2012. Available at: [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2012/2012\\_164-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2012/2012_164-eng.php). Accessed on November 4, 2012.

(2) Swissmedic. COMMUNIQUÉ DE PRESSE Vaccins antigrippaux de Novartis : Swissmedic donne son feu vert October 31, 2012. Available at: <http://www.swissmedic.ch/aktuell/00003/02075/index.html?lang=fr>. Accessed on November 4, 2012.

(3) World Health Organization. Influenza (Seasonal), Fact sheet N°211. April 2009. Available at: <http://www.who.int/mediacentre/factsheets/fs211/en/>. Accessed on November 4, 2012.

(4) Andre, FE, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bulletin of the World Health Organization volume 86, Number 2, 2008. Available at: <http://www.who.int/bulletin/volumes/86/2/07-040089/en>. Accessed on November 4, 2012.

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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 9, 2012

By: /s/ MALCOLM B. CHEETHAM

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