

NOVARTIS AG  
Form 6-K  
November 01, 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 October 31, 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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**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

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

**Health Canada and Swissmedic lift precautionary holds on Novartis seasonal influenza vaccines**

- *Agrippal® and Flud® safety and efficacy reaffirmed following additional analysis*
- *Patients are Novartis' highest priority – the company continues to work with other countries to resolve open questions and resume distribution as soon as possible*
- *Vaccination is the most effective way to help protect against seasonal influenza, which leads to three to five million cases of severe illness and about 250,000 to 500,000 deaths worldwide each year*

**Basel, October 31, 2012** Novartis welcomes the decisions by Health Canada and Swiss Agency for Therapeutic Products, Swissmedic, to lift the precautionary holds on the distribution of Novartis seasonal influenza vaccines Agrippal® and Flud®. This follows additional analysis to reaffirm the safety and efficacy of the vaccines.

According to its public statement, Health Canada looked at the results of its own testing, conducted a health risk assessment, and reviewed information from its European partners and data submitted by Novartis in making its decision. None of the information reviewed indicated a safety issue.

([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))

Swissmedic indicated that it came to a similar determination following additional analyses and clarification provided by Novartis, together with analyses of samples in its own laboratory that confirmed the quality of the vaccines.

(<http://www.swissmedic.ch/aktuell/00003/02075/index.html?lang=fr>)

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Patients are at the center of everything we do and their safety is our highest priority. We are pleased that the precautionary holds in Canada and Switzerland have been lifted, said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. We have remained confident in the safety and efficacy of our vaccines; now we are focused on resuming distribution as soon as possible to protect against seasonal influenza.

The safety and efficacy of these seasonal influenza vaccines are supported by the clinical data gathered during the 2012-2013 seasonal influenza studies required for licensure. For the current season, more than one million doses have been administered and no unexpected adverse events have been reported.

Novartis is working diligently with other local health authorities who implemented similar precautionary measures to address their questions and plan to restore distribution as soon as possible.

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

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as continues to work, confident, is working, plan, or similar expressions, or by express or implied discussions regarding the potential resumption of Agrippal and Fluad 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 Fluad. 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 Fluad will be resumed in the countries where its distribution was suspended, or that any such resumption will take place at any particular time. Nor can there be any guarantee that 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'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: October 31, 2012

By: /s/ MALCOLM B. CHEETHAM

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