NOVARTIS AG
Form 6-K
October 26, 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 25, 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

Novartis International AG

Novartis Global Communications
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http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis confident in safety and efficacy of its seasonal influenza vaccines produced in Italy

- *As precaution, Italian ministry of health temporarily halts distribution of two seasonal influenza vaccines Agrippal and Fluad, produced at Novartis site in Italy*

- *Recent clinical trials of these influenza vaccines and administration during seasonal vaccination campaigns have shown no unexpected adverse events to date*

- *Novartis is proactively engaging with health authorities to address the situation*

- *Patient safety is highest priority at Novartis*

Basel, October 25, 2012 Novartis confirms its confidence in the safety and efficacy of its seasonal influenza vaccines Agrippal® and Fluad® manufactured in Italy. Patient safety is of the highest priority to Novartis. Novartis internal assessments and the clinical data gathered during the 2012-2013 seasonal influenza studies required for European licensure of Agrippal and Fluad demonstrate a safety and immunogenicity profile similar to that of prior years. To date, data from the ongoing seasonal vaccination campaign have revealed no safety signals.

The Italian ministry of health took this precautionary measure following a report by Novartis of small particles in the vaccines. Recently, Novartis voluntarily provided the Italian health authorities with its assessments supporting the quality, efficacy and safety of the specific vaccines in question. Novartis confirms that these particles can occur in the vaccine manufacturing process and is confident that there is no impact on the safety or efficacy of the vaccine.

The company will continue to work with the Italian Ministry of Health and AIFA to understand the reasons for their decision and to clarify any questions. The company is fully committed to providing high quality vaccines to patients and will continue to work with the authorities to make vaccines available.

Novartis will provide further updates when more information is available. For more information visit www.novartisvaccines.com/fluinfo.

Agrippal and Fluad are not available in the United States of America and marketed in Germany under the tradename Begrippal® and in Italy additionally under the tradenames Influpozzi sub unità and Influpozzi adiuvato.

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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For Novartis multimedia content, please visit www.thenewsmarket.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 25, 2012

By: /s/ MALCOLM B. CHEETHAM

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