NOVARTIS AG
Form 6-K
January 10, 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 January 8th 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

Novartis Consumer Health Inc. voluntarily recalls certain over-the-counter products in the US while Novartis Group strengthens quality standards across all manufacturing sites

- *The voluntary recall is precautionary following consumer complaints of chipped and broken pills and inconsistent bottle packaging line clearance practices possibly resulting in mixed tablets*

- *There have been no related adverse events reported with the issues leading to the recall*

- *US Consumers are asked to either destroy or return unused product identified in the recall to Novartis Consumer Health Inc.*

- *To accelerate improvements at its Lincoln, Nebraska facility, Novartis Consumer Health has temporarily suspended operations as well as shipments from the site*

- *A one-time charge currently estimated at USD 120 million related to the recall and improvement efforts will be taken in the fourth quarter of 2011 by Novartis Consumer Health Inc.*

- *Novartis is fully committed to maintaining high quality standards of its products*

Basel, January 8, 2012 Novartis Consumer Health Inc. (NCH) informed customers, that it is voluntarily recalling all lots of select bottle packaging configurations from retailers of Excedrin® and NoDoz® products with expiry dates of December 20, 2014 or earlier as well as Bufferin® and Gas-X Prevention® products with expiry dates of December 20, 2013 or earlier, in the United States. NCH is taking this action as a precautionary measure, because the products may contain stray tablets, capsules, or caplets from other Novartis products, or contain broken or chipped tablets.

Information on the affected bottle sizes, and related expiry dates will be available at www.novartisOTC.com as of January 9, 2012. This precautionary recall follows the recent voluntary suspension of operations and shipments from Novartis Consumer Health Inc s Lincoln, NE facility. These actions were taken to accelerate maintenance and other improvement activities at the site.

There have been no related adverse event reports received as a result of these issues. The established safety profile for each of these products remains consistent. Mixing of different products in the same bottle could result in consumers taking the incorrect product and receiving a higher or lower strength than intended or receiving an unintended ingredient. This could potentially result in overdose, interaction with other medications a consumer may be taking, or an allergic reaction if the consumer is allergic to the unintended ingredient. NCH is not aware of adverse events reported with the issues leading to the recall. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA) and Novartis Consumer Health will continue to work closely with the agency as well as its customers throughout this process.

We are committed to a single quality standard for the entire Novartis Group and we are making the necessary investments and committing the right resources to ensure these are implemented across our entire network, said Joseph Jimenez, CEO of Novartis. The high quality of our products and operations has been critical to building the Novartis reputation over the past 15 years. We are committed to ensuring the highest standard for patients who rely on our products and medicines.

NCH is recalling these products as a precaution due to an internal product review and complaints that identified issues such as broken gelcaps, chipped tablets and inconsistent bottle packaging line clearance practices, where a potential for a tablet mix up could not be ruled out.

NCH plans to gradually resume operations at its Lincoln, NE site following implementation of planned improvements and in agreement with the FDA. The Novartis Consumer Health Inc. Lincoln, NE facility produces a variety of products mainly for the US market with annual sales value of less than 2% of Novartis Group sales. At this stage, it is not possible to determine when the plant will resume full operations and the full financial impact of these events. NCH will take a one-time charge currently estimated at USD 120 million in the fourth quarter of 2011, relating to the recalls and improvement work at the Lincoln, NE facility.

Novartis commitment to quality

Novartis Group is fully committed to ensure the quality, safety and integrity of its products. All Novartis Group companies have a clear commitment to patients and Health Authorities to ensure high quality standards for all our products and services. Novartis Group stands behind the safety and efficacy of its products, and is fully committed to maintaining high quality standards at all production sites in the US and around the world. All Novartis Group products are subjected to strict manufacturing, testing and monitoring standards. Where they fall outside the standards, Novartis Group companies take actions to correct the issue and may recall products as a precaution.

Note to US consumers and customers

Consumers and customers in the US who have questions can call the Consumer Relationship Center at 1-888-477-2403 (available Monday-Friday 9 a.m. to 8 p.m. Eastern Time).

For more detailed information regarding the product, potential drug reactions, impacted configurations, related NDC numbers and expiry dates, please visit our website starting January 9, 2012 at www.novartisOTC.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as committed , plans , will or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Excedrin, Bufferin, Gas-X Prevention and NoDoz or regarding potential future revenues from Excedrin, Bufferin, Gas-X Prevention and NoDoz. 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 Excedrin, Bufferin, Gas-X Prevention and NoDoz to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Excedrin, Bufferin, Gas-X Prevention and NoDoz will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Excedrin, Bufferin, Gas-X Prevention and NoDoz will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Excedrin, Bufferin, Gas-X Prevention and NoDoz 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; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general publi 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 Group 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 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. Novartis Group companies employ approximately 121,000 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: January 8th 2012

By: /s/ MALCOLM B. CHEETHAM

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