NOVARTIS AG
Form 6-K
November 13, 2006

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 13, 2006

(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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- Investor Relations Release -

Novartis announces three-month extension of US regulatory review for Galvus® to assess recently available clinical data

- ***Substantial new short- and long-term data being submitted to US Food and Drug Administration (FDA)***

- ***Novartis committed to working closely with the FDA to gain approval for Galvus, which has been studied in more than 7,000 people to date***

Basel, November 13, 2006 - Novartis announced today a three-month extension in the US regulatory review period for the oral anti-diabetes medicine Galvus (vildagliptin) until the end of February 2007 after deciding to submit recently available clinical data to the US Food and Drug Administration (FDA).

These additional data being submitted to the FDA add about 1,000 patient years of treatment experience with Galvus. These recently available data include results from short- and long-term studies for periods of up to two years, both as a monotherapy or in combination with other anti-diabetes medicines.

These new data further support the proposed dosing regimen and indications as well as complement the risk/benefit profile of Galvus. In particular, they provide further evidence confirming data submitted earlier to the FDA showing that skin findings identified in a single species during a preclinical animal study have not been seen in clinical studies with patients treated for type 2 diabetes.

We are confident of the efficacy and safety of Galvus and in gaining US approval, said James Shannon, M.D., Head of Development at Novartis Pharma AG. We believe this additional information being provided to the FDA will strengthen the already robust data supporting Galvus as a new and needed treatment option for patients with type 2 diabetes.

Novartis is committed to working closely with the FDA in its review of Galvus, which the agency accepted for review in March 2006 after Novartis made the filing in January 2006. The FDA has the option of extending the typical 10-month review period for new drugs if a company submits significant additional data during the last three months of the review. An extensive clinical trial program is ongoing for Galvus.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as will, believe , we are confident , remains confident or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular, management s expectations relating to the FDA review of Galvus could be affected by, among other things, uncertainties relating to the review of additional clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures, as well as factors discussed in the Company s Form 20-F filed with the US Securities and Exchange Commission. 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.

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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 13, 2006

By: /s/ MALCOLM B. CHEETHAM

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