

NOVARTIS AG  
Form 6-K  
December 14, 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 December 14, 2006**

(Commission File No. 1-15024)



**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

4056 Basel

**Switzerland**

(Address of Principal Executive Offices)

Edgar Filing: NOVARTIS AG - Form 6-K

---

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

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis announces three-month extension of US regulatory review period for Tekturna®**

- *Tekturna seeking to become first drug in a new class of high blood pressure medicines*
- *Extension provides FDA time to review new clinical data supporting safety profile of Tekturna*
- *Novartis committed to working closely with FDA to gain approval for Tekturna, which has been studied in more than 6,000 people to date*

**Basel, December 14, 2006** - Novartis announced today that the US regulatory review period has been extended by up to three months for Tekturna® (aliskiren), which was submitted for approval earlier in 2006 to become the first in a new class of high blood pressure medicines for more than a decade.

The extension will provide the US Food and Drug Administration (FDA) with time to consider additional clinical data submitted by Novartis in early December. These data come from a study involving 30 healthy volunteers who received Tekturna at the proposed 300 mg once-daily dose for eight weeks to study potential changes of the colonic mucosa. Analysis of the data indicated that Tekturna did not induce any changes in the mucosal lining of the colon, as evaluated by colonoscopy and biopsies.

Novartis is confident that providing this additional information to the FDA will help secure approval for Tekturna in the US and allow for this important therapy to be offered to patients seeking to gain control of high blood pressure. Tekturna was developed in collaboration with Speedel.

**Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as seeking to become, committed, to become, will provide, potential, confident, will help secure approval, to be offered, seeking, or similar expressions, or implied discussions regarding potential future approvals or future sales of Tekturna. Such statements reflect the current views of the Novartis with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Tekturna will be approved for sale in any market, or that it will reach any particular sales levels. In particular, management's expectations regarding the approval and commercialization of Tekturna could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; competition in general; increased government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 AG 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>.

###

**Media Relations**

**Richard Booton**

Novartis Pharma Communications

+41 61 324 4356 (direct)

+41 79 753 2593 (mobile)

[richard.booton@novartis.com](mailto:richard.booton@novartis.com)

**Corinne Hoff**

Novartis Global Media Relations

+41 61 324 9577 (direct)

+41 61 324 2200 (main)

[corinne.hoff@novartis.com](mailto:corinne.hoff@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

**Investor Relations**

**International**

**Ruth Metzler-Arnold**

Katharina Ambühl

Nafida Bendali

Jason Hannon

Richard Jarvis

Silke Zentner

+41 61 324 7944

+41 61 324 5316

+41 61 324 3514

+41 61 324 2152

+41 61 324 4353

+41 61 324 8612

**North America**

**Ronen Tamir**

Arun Nadiga

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2444

+1 212 830 2445

+1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**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: December 14, 2006

By:

/s/ Malcolm B. Cheetham

Name:

Malcolm B. Cheetham

Title:

Head Group Financial  
Reporting and Accounting