NOVARTIS AG
Form 6-K
September 28, 2007

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 September 27, 2007

(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
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Prexige® receives not approvable letter in the US despite being one of the most studied COX-2 inhibitors

Novartis to continue discussions with FDA and believes Prexige a valuable treatment option for appropriate patients with osteoarthritic pain

Extensive clinical trial data involving approximately 40,000 patients show significant reduction in serious upper gastrointestinal complications

Prexige shown to have significantly less impact on blood pressure than the non-steroidal anti-inflammatory drugs (NSAIDs) naproxen and ibuprofen

Number of patients (0.85%) with elevated liver enzymes greater than three times the upper limit of normal in line with other currently available NSAIDs

Basel, September 27, 2007 Novartis has received a not approvable letter from the US Food and Drug Administration (FDA) for its COX-2 inhibitor Prexige® (lumiracoxib) as a once-daily treatment for patients suffering from osteoarthritic pain.

The FDA s response came despite a clinical trial database for Prexige that comprises approximately 40,000 patients and is one of the largest bodies of evidence for any drug in this class.

In particular, results of the TARGET study involving more than 18,000 patients showed Prexige reduced the incidence of serious upper gastrointestinal complications by 79% compared to two widely-used non-steroidal anti-inflammatory drugs (NSAIDs) in patients not taking aspirin(1).

(1) Schnitzer TJ, et al, on behalf of the TARGET Study Group. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: a randomised controlled trial. Lancet 2004;

364(9435):665-674.

TARGET also showed Prexige was associated with significantly smaller increases in blood pressure than the NSAIDs naproxen and ibuprofen, with no significant difference in cardiovascular events such as heart attack or stroke(2).

(2) Farkouh M, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: a randomized controlled trial. Lancet. 2004; 364(9435): 675-684.

Many patients cannot tolerate the gastrointestinal side effects associated with NSAID pain treatments, such as those suffering from ulcers or who are being treated with anti-coagulants like warfarin, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. We believe Prexige remains an important therapy for appropriate patients with osteoarthritic pain, and we will continue discussions with the FDA.

At the FDA s request, Novartis submitted clinical data on the liver profile of the proposed 100 mg once-daily dose studied over 12 months of therapy. The results showed 0.85% of patients had elevations of the liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) of greater than three times the upper limit of normal, which is similar to levels observed with currently available NSAIDs. There were also no cases of jaundice or hepatic failure on Prexige

100 mg once-daily dosing in the clinical development program. Despite this data, the FDA deemed Prexige not approvable.

The FDA noted in its response that it remained open to exploring the use of this medicine in patients where Prexige would provide an acceptable benefit-to-risk balance. This group could include patients with a higher incidence of gastrointestinal complications, including those suffering from ulcers or being treated with anticoagulants.

Prexige is currently approved in more than 50 countries. An alternative trade name for this medicine has been submitted for US regulatory approval.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as not approvable , continue , believes , believe , will , remained open to exploring , would , could , or similar expressions, or by express or implied discussions regarding the potential approval of Prexige (lumiracoxib) in the US or other markets, or regarding potential future revenues from Prexige (lumiracoxib). Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Prexige (lumiracoxib) to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Prexige (lumiracoxib) will be approved for sale in the US or in other additional markets. Nor can there be any guarantee that Prexige (lumiracoxib) will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Prexige (lumiracoxib) 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 public debate and regulatory activity regarding COX-2 inhibitors like Prexige (lumiracoxib); competition in general; 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 (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

# # #

Novartis Media Relations

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 14008 (mobile)
john.gilardi@novartis.com

Irina Ferluga
Novartis Pharma Communications
+ 41 61 324 2422 (direct)
+ 41 79 824 1121 (mobile)
irina.ferluga@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International
Ruth Metzler-Arnold
Katharina Ambuehl
Nafida Bendali
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis

Central phone no: +41 61 324 7944
e-mail: investor.relations@novartis.com

North America

Ronen Tamir	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: 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: September 27, 2007

By: /s/ MALCOLM B. CHEETHAM
Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting