

NOVARTIS AG
Form 6-K
November 20, 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 November 19, 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):

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Yes: ☐ No: ☒

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Yes: ☐ No: ☒

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: ☐ No: ☒

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

United Kingdom and Germany suspend marketing and sale of Prexige® pending outcome of European regulatory review

Suspensions in UK and Germany come as European Union regulators initiate so-called Article 107 procedure to review drug's benefit/risk profile

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

Basel, November 19, 2007 Health regulators in the United Kingdom and Germany have suspended the marketing and sale of Prexige® (lumiracoxib), a COX-2 inhibitor for patients with osteoarthritic pain, following a review of the drug's benefit/risk profile.

Novartis is informing regulatory agencies around the world of these changes, which come after similar actions in other countries in recent months. Novartis will also comply with a request from the Austrian health authority to suspend sales pending a final decision by the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines in the European Union.

Patients taking Prexige in the UK, Germany and Austria should consult their healthcare provider.

Prexige is available in some European countries as a 100 mg once-daily treatment for osteoarthritic pain following EU approval through the Mutual Recognition Procedure (MRP) in October 2006, with the UK as the reference member state. Prexige is also marketed and sold in Belgium, Cyprus, Hungary, Malta, Portugal and Sweden. In the first nine months of 2007, Prexige had net sales of USD 8 million in Europe.

The suspensions were announced today after the CHMP initiated a so-called Article 107 procedure on November 16. This occurs when an EU member state withdraws, suspends or changes the status of a nationally authorized medicine after a review of safety data. This enables the CHMP to prepare an opinion as to whether the regulatory action should apply throughout the EU.

Other EU countries may decide to independently suspend the marketing authorization or sale of Prexige ahead of a decision by the CHMP, which is expected in December.

Liver enzyme changes are a known side effect of all COX-2 inhibitors and traditional non-steroidal anti-inflammatory drugs (NSAIDs). Available data suggest that Prexige 100 mg once-daily for osteoarthritis is not associated with increased hepatic (or liver) risk compared to other NSAIDs.

The latest analysis of patients taking the Prexige 100 mg dose showed nine severe hepatic events reported worldwide. This corresponds to a rate of 5.19 events per 100,000 patient-years, which is

within the rate expected for NSAIDs. Although a direct comparison cannot be made between spontaneous reports and epidemiological data, a major analysis of epidemiological studies on NSAID-induced liver injury resulting in hospitalization showed an incidence rate of between 3.1 and 23.4 per 100,000 patient-years(1).

The actions in Europe come after an Urgent Safety Restriction was initiated in August 2007 for the Prexige 100 mg dose. Novartis worked with European regulators to update prescribing information, including additional warnings and precautions about liver monitoring for patients. Prexige was first withdrawn in August 2007 in Australia where a number of liver side effects were reported, including two deaths, associated with the use of Prexige at doses higher than 100 mg. No deaths have been reported worldwide with the 100 mg dose.

Prexige is the only selective COX-2 inhibitor or NSAID to be shown to demonstrate gastrointestinal (GI) benefit in patients with osteoarthritis in a large outcome study versus other NSAIDs, decreasing serious GI ulcer complications (including bleeds) by over 70%. NSAID-related serious GI ulcer complications occur more frequently than hospitalization for hepatic complications. Approximately 1,000 deaths related to GI ulcerations from NSAIDs occur in the UK each year(2).

Novartis continues to believe Prexige is an important treatment option with a positive benefit/risk ratio when used in appropriate patients. Novartis will continue discussions with European health regulators, and with the US Food and Drug Administration following its decision in September 2007 not to approve Prexige, to determine how to make this treatment option available to appropriate patients.

Disclaimer

The foregoing press release contains forward-looking statements such as will, may, or similar expressions, or by express or implied discussions regarding the results of the pending regulatory review in Europe, potential future discussions with regulators, regulatory filings, decisions or approvals or potential future sales of Prexige (lumiracoxib). Such forward-looking statements reflect the current views of Novartis 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 any future regulatory filings will satisfy regulatory requirements regarding Prexige (lumiracoxib), that Prexige (lumiracoxib) will be approved for any indications or labeling in any additional markets or that Prexige (lumiracoxib) will reach any particular level of sales. In particular, management's expectations regarding Prexige (lumiracoxib) could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the public debate and regulatory activity regarding COX-2 inhibitors like Prexige (lumiracoxib); unexpected clinical trial results, including unexpected additional analysis of existing clinical data and unexpected new clinical data; government, industry, and general public pricing pressures; competition in general; Novartis' ability to obtain or maintain patent or other proprietary intellectual property protection; as well as other risk factors discussed in Novartis AG's Form 20-F filed with the U.S. 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document 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 approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

1 Rubenstein JH, Laine L. Systematic review: the hepatotoxicity of non-steroidal anti-inflammatory drugs. *Aliment Pharmacol Ther* 2004; 20: 373-380. doi: 10.1111/j.1365-2036.2004.02092.x

2 Hawkey CJ, Langman MJS. Non-steroidal anti-inflammatory drugs: overall risks and management. Complementary roles for COX-2 inhibitors and proton pump inhibitors. *Gut* 2003;52:600-608.

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Novartis Media Relations

John Gilardi

Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 1408 (mobile)
john.gilardi@novartis.com

e-mail: media.relations@novartis.com

Irina Ferluga

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

Novartis Investor Relations

International

Ruth Metzler-Arnold

Katharina Ambuehl
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis
Isabella Zinck

Central phone no: +41 61 324 7944

e-mail: investor.relations@novartis.com

North America

Ronen Tamir

Jill Pozarek
Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+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: November 19, 2007

By: /s/ MALCOLM B. CHEETHAM

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