

NOVARTIS AG  
Form 6-K  
July 23, 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 July 20, 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:  Form 40-F:

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:  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 -

**Exelon® skin patch recommended for European approval, the first use of this new technology to treat patients with Alzheimer's disease**

- *Once-daily patch offers novel approach to treating Alzheimer's disease, providing smooth and continuous delivery of drug over 24 hours(1)*
- *Similar efficacy to highest doses of Exelon capsules with significant improvement in memory and ability to perform everyday activities compared to placebo(1)*
- *Designed with compliance in mind and preferred by caregivers, helping them manage patient care and giving visual reassurance of treatment(2)*
- *Minimizes gastrointestinal side effects seen with oral form of drug(1)*

**Basel, July 19, 2007** A patch that delivers Exelon®, an effective Alzheimer's disease medication, through the patient's skin has been recommended for approval in the European Union – the first time this technology has been applied to treat the disease in the EU.

Exelon (rivastigmine transdermal patch) received a positive opinion for treating mild to moderately severe forms of Alzheimer's disease from the Committee for Medicinal Products for Human Use (CHMP), the body that reviews drug applications for all 27 EU member states as well as Iceland and Norway.

This announcement comes on the same day that the CHMP recommended approval for two other Novartis medicines, Galvus® (vildagliptin) for type 2 diabetes and Aclasta® (zoledronic acid 5 mg) for postmenopausal osteoporosis. So far this year Novartis has received a total of seven product approvals and four positive opinions from the US and European regulatory authorities, providing innovative treatments to patients and creating a strong new growth platform.

The European Commission generally follows the recommendation of the CHMP and is expected to issue a decision on Exelon patch within three months. The announcement comes a few weeks after this medicine was approved in the US.

Exelon patch offers unique therapeutic benefits because it maintains steady drug levels in the bloodstream, improves tolerability and allows a higher proportion of patients to receive therapeutic doses of medication, said Alexander Kurz, MD, Professor of Psychiatry and Head of the Centre for Cognitive Disorders at the Department of Psychiatry and Psychotherapy of Technische Universität München, Munich, Germany.

Coupled with the clear benefits for caregivers in terms of ease of administration, it represents a significant advance in the treatment of Alzheimer's disease. We look forward to the time when this important new therapy will be available throughout the EU, Dr. Kurz said.

Alzheimer's disease is a progressive disorder that alters the brain, causing impaired memory, thinking and behavior, and is estimated to affect 18 million people worldwide<sup>(3)</sup>. The patch is applied to the back, chest or upper arm, and provides smooth and continuous delivery of medication through the skin over 24 hours with the potential for improved efficacy<sup>(1)</sup>.

A key attribute of Exelon patch is a sharp reduction in gastrointestinal side effects commonly seen with the oral forms of this class of drugs called cholinesterase inhibitors. In a clinical trial these side effects were greatly reduced, with three times fewer reports of nausea and vomiting than with the capsule form of the drug<sup>(1)</sup>.

Designed with compliance in mind, Exelon patch was preferred to capsules by more than 70% of caregivers in a clinical study as a method of drug delivery because it helped them follow the treatment schedule, interfered less with their daily life, and was easier to use overall than an oral medication<sup>(2)</sup>.

The positive recommendation in Europe, coming so soon after the US approval, highlights the tremendous importance of Exelon patch as an innovative way of delivering a proven medicine, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. The patch offers visual reassurance that the medication has been given, and helps caregivers cope with the daily challenges of looking after someone with this devastating disease.

The EU positive opinion was based on results from the international IDEAL (Investigation of Transdermal Exelon in Alzheimer's disease) trial, which showed that patients receiving the Exelon patch demonstrated improved memory, overall functioning, and ability to perform everyday activities than those taking placebo<sup>(1)</sup>.

Since 1997, Exelon (rivastigmine) has been used to treat mild to moderate Alzheimer's disease in more than 70 countries. Exelon is the only cholinesterase inhibitor to be approved for both mild to moderate Alzheimer's disease and Parkinson's disease dementia in both Europe and the US. The US Food and Drug Administration approved Exelon®Patch (rivastigmine transdermal system) on July 6 for the treatment of both mild to moderate Alzheimer's disease and Parkinson's disease dementia.

Alzheimer's disease affects one in 10 people over the age of 65, making it the most common form of dementia and the third leading cause of death in this age group behind cardiovascular disease and cancer<sup>(3)</sup>. The global direct costs of dementia were estimated at USD156 billion in 2003<sup>(4)</sup>.

#### **Disclaimer**

This release contains certain forward-looking statements relating to the Novartis Group's business, which can be identified by the use of forward-looking terminology such as "generally follows", "potential", "expected", "look forward to the time", similar expressions, or "express or implied" discussions regarding potential future regulatory approvals or submissions with respect to, or future sales of, Exelon or the Exelon patch. 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 the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that the Exelon patch will be approved for sale in the EU or in any additional markets or that the Exelon patch will reach any particular sales levels. In particular, management's expectation regarding the Exelon patch 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; government, industry, and general public pricing pressures; competition in general; the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed 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 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 more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

#### **References**

- (1) Winblad B, Cummings J, et al. A 6-Month Double-blind, Randomized, Placebo-Controlled Study of a Transdermal Patch in Alzheimer's Disease - Rivastigmine Patch versus Capsule. *International Journal of Geriatric Psychiatry* May 2007; 22: 5:485-491.
- (2) Winblad B, Cummings J, et al. Caregiver Preference For Rivastigmine Patch Relative to Capsule For Treatment of Probable Alzheimer's Disease. *International Journal of Geriatric Psychiatry* May 2007; 22: 5: 456-67.
- (3) Alzheimer's Association. Alzheimer's Disease Facts and Figures, 2007.
- (4) Wimo A, Jonsson L, Winblad B. An Estimate of the Worldwide Prevalence and Direct Costs of Dementia in 2003. *Dementia and Geriatric Cognitive Disorders* 2006; 21:175-181.

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**Novartis Media Contacts**

**Corinne Hoff**

Novartis Global Media Relations  
+41 61 324 9577 (direct)  
+41 79 248 5717 (mobile)  
corinne.hoff@novartis.com

**Julie Morrow**

Novartis Pharma Communications  
+41 61 324 1135 (direct)  
+41 79 596 4636 (mobile)  
julie.morrow@novartis.com

e-mail: media.relations@novartis.com

**Novartis Investor Relations**

**International**

<b>Ruth Metzler-Arnold</b>	+41 61 324 7944
Katharina Ambühl	+41 61 324 5316
Nafida Bendali	+41 61 324 3514
Jason Hannon	+41 61 324 2152
Thomas Hungerbuehler	+41 61 324 8425
Richard Jarvis	+41 61 324 4353

**North America**

<b>Ronen Tamir</b>	+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: July 20, 2007

By: /s/ Malcolm B. Cheetham

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