NOVARTIS AG
Form 6-K
July 20, 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 July 19, 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

Novartis International AG
Novartis Communication
CH-4002 Basel
Switzerland

**- Investor Relations Release -**

**Exelon Patch, the first transdermal therapy for Alzheimer s disease, may provide promising new approach to treatment of dementia**

*IDEAL study shows potential of once-daily Exelon Patch for improving memory and maintaining everyday activities of Alzheimer s patients*

*Over 70% of caregivers preferred patches to capsules due to better compliance and less interference with daily lives*

*Alzheimer s disease the most common form of dementia, affects an estimated 15 million people worldwide*

**Basel, July 19, 2006** - An international study of the first transdermal patch for patients with Alzheimer s - a degenerative brain disease estimated to affect more than 15 million people worldwide - has shown that it may provide a promising new treatment approach(1).

The six-month IDEAL trial of 1,195 patients with Alzheimer s disease showed that the ExelonÒ Patch provided benefits across a range of symptoms and the target dose was well tolerated. Results were presented today at the 10th International Conference on Alzheimer s Disease and Related Disorders (ICAD), presented by the Alzheimer s Association in Madrid, Spain.

Patients receiving Exelon Patch (rivastigmine transdermal patch) had significant improvements in memory and were better able to maintain everyday activities(1) than those receiving placebo. They could also complete a concentration task up to 20 seconds faster compared to those taking placebo, and physicians considered Exelon Patch patients to have done better overall.

In addition, over 70% of caregivers in the IDEAL study preferred the patch to capsules as a method of drug delivery for reasons including helping them follow the treatment schedule, overall ease of use and less interference with daily life(2), according to a questionnaire in the study.

The patch represents an important new option for people with Alzheimer s disease and their families, said lead study investigator Professor Bengt Winblad of the Karolinska Institute in Stockholm, Sweden. The target rivastigmine patch dose provided similar efficacy to that achieved at the highest doses of the capsule with three times fewer reports of nausea and vomiting. A transdermal patch may prove to be the best way to deliver rivastigmine to treat Alzheimer s.

Transdermal patches are designed to provide controlled, continuous delivery of drug through the skin. This maintains steady drug levels in the bloodstream, which may reduce side effects and

consequently allow access to higher doses. In addition, patches may help caregivers to monitor treatment compliance because they provide visual reassurance that the medication has been taken.

Although Alzheimer s disease treatments have been available in oral forms for some time, we believe a patch may offer unique advantages for patients with this condition, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. If approved, the Exelon Patch could potentially improve therapy compliance and help patients and their caregivers in reaching a better quality of life.

Exelon is a cholinesterase inhibitor already approved in many countries for the treatment of mild to moderate Alzheimer s disease and dementia associated with Parkinson s disease. The IDEAL results will support the regulatory submission of the Exelon Patch to health authorities, planned by the end of 2006.

**About the IDEAL study**

IDEAL (Investigation of Transdermal Exelon in Alzheimer s disease) was a 24-week, multi-center, randomized, double-blind, placebo- and active-controlled trial to compare the efficacy, safety and tolerability of the once-daily Exelon Patch with conventional twice-daily Exelon capsules in patients with moderate Alzheimer s disease. The primary outcomes measures were the Alzheimer s Disease Assessment Scale - cognitive subscale (ADAS-cog) and Alzheimer s Disease Cooperative Study - Clinical Global Impression of Change (ADSC-CGIC).

IDEAL was conducted in 21 countries and involved 100 centers and 1,195 patients aged 50-85 years old with a score of 10-20 in the Mini-Mental State Examination (MMSE), the most widely-used test for assessing memory problems or dementia. Patients received Exelon either in capsules (6 mg twice-daily) or patches in two sizes, namely Patch 10 (providing 9.5 mg over 24 hours) or Patch 20 (17.4 mg/24 h)(1).

Both patch sizes showed superior efficacy to placebo. The target dose of Patch 10 showed similar efficacy to the highest doses of Exelon capsules with three times fewer reports of nausea (7.2 percent vs. 23.1 percent) and vomiting (6.2 percent vs. 17.0 percent), which are well-known side effects of cholinesterase inhibitors. Patch 20 showed numerically but not statistically improved cognitive scores versus capsules and similar tolerability to capsules.

Local skin tolerability was good. The percentage of patients who reported moderate or severe redness of the skin at any point of the study was only 7.6 percent and 6.2 percent of patients receiving Patch 10 and 20, respectively. The patch also demonstrated very good skin adhesion over 24 hours in a range of everyday situations such as bathing and in hot weather.

**About Exelon**

Since 1997, Exelon (rivastigmine tartrate) has been widely used to treat mild to moderate Alzheimer s disease in more than 70 countries. Exelon is the only cholinesterase inhibitor to be also approved to treat both Alzheimer s disease and dementia associated with Parkinson s disease (PDD) in Europe and US.

Exelon belongs to a class of drugs known as cholinesterase inhibitors (ChEIs) which increase the activity of the neurotransmitter acetylcholine in the brain. Among the widely-used ChEIs, Exelon is the only treatment that inhibits both enzymes involved in the breakdown of this neurotransmitter - acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE). This may offer additional benefits over treatments which inhibit AChE alone. Exelon can maintain both memory and thinking, help with behavioural problems, and affect how patients cope with the activities of daily living. It may help them communicate better, interact socially, and participate in hobbies and activities of daily living(3),(4).

**About Alzheimer s disease**

Alzheimer s disease is a progressive, degenerative disease that alters the brain, causing impaired memory, thinking and behaviour. Affecting approximately 15 million people worldwide and two to six percent of those over 65 years of age, it is the most common form of dementia and the third leading cause of death in this age group behind cardiovascular disease and cancer(5). The worldwide direct costs for dementia in 2003 are estimated at $156 billion(5).

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 may , will , could , if approved , planned by , or similar expressions, or by express or implied discussions regarding potential future regulatory submissions for Exelon or the Exelon Patch, or regarding potential future revenue from Exelon or the Exelon Patch. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Exelon or the Exelon Patch to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any regulatory submissions regarding the Exelon Patch will be made as planned or, if made, will be successful. Neither can there be any guarantee regarding potential future revenue from Exelon or the Exelon Patch. In particular, management s expectations regarding commercialization of Exelon or the Exelon Patch could be affected by, among other things, additional analysis of Exelon clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays in government regulation generally; the ability of Novartis to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; 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 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 has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer s disease, Parkinson s disease, attention deficit/hyperactivity disorder, epilepsy, schizophrenia and migraine. Novartis continues to be active in the research and development of new compounds, and is committed to addressing unmet medical needs and to supporting patients and their families affected by these disorders.

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 96,000 people 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. IDEAL: a 24 week placebo controlled study of the first transdermal patch in Alzheimer s disease - rivastigmine patch versus capsule. Oral Presentation at the 10th International Congress of Alzheimer s and Related Disorders (ICAD), Madrid, Spain, 19 July 2007.

(2). Winblad B, Beusterien KM, et al. Caregivers prefer patches to capsules: results from a 24-week placebo controlled study of rivastigmine (IDEAL trial). Poster presented at the 10th International Congress of Alzheimer s and Related Disorders (ICAD), Madrid, Spain, 19 July 2007.

(3). Corey-Bloom J, Anand R, Veach J. A randomized trial evaluating the efficacy and safety of ENA713 (rivastigmine tartrate), a new acetylcholinesterase inhibitor, in patients with mild to moderately severe Alzheimer s disease. Int J Geriatr Psychopharmacol 1998;1:55-65.

(4). Rösler M, Anand R, Cicin-Sain A et al. Efficacy and safety of rivastigmine in patients with Alzheimer s disease: international randomized controlled trial. Br Med J 1999;318:633-40.

(5). Wimo A, Jonsson L, Winblad B, An Estimate of the Worldwide Prevalence and Direct Costs of Dementia in 2003, dementia and Geriatrics Cognitive Disorders, 2006, 21: 175-181.

# # #

**Novartis Global Investor Relations**

| | | |
|---|---|---|
| **Jean-Jacques Charhon,** | Global Head IR ad interim | +41 61 324 79 44 |
| Katharina Ambühl | | +41 61 324 53 16 |
| Nafida Bendali | | +41 61 324 35 14 |
| Richard Jarvis | | +41 61 324 43 53 |
| Silke Zentner | | +41 61 324 86 12 |
| **Ronen Tamir** | | +1 212 830 24 33 |
| Jill Pozarek | | +1 212 830 24 45 |

**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 19, 2006

By: /s/ MALCOLM B. CHEETHAM

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