NOVARTIS AG
Form 6-K
August 18, 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 August 17, 2006**

**(Commission File No. 1-15024)**

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# Novartis AG

**(Name of Registrant)**

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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

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Yes: o **No**: x

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**- Investor Relations Release -**

**Novartis seeks European approval for Galvus®, an innovative oral treatment for people with type 2 diabetes**

- ***Clinical studies demonstrate impressive blood sugar lowering effects, even among difficult-to-treat patients***
- ***Data show HbA1c reduced by up to 1.8% when used as monotherapy***
- ***Galvus novel mechanism of action targets pancreatic islet dysfunction, a causal factor in diabetes not addressed by current therapies***
- ***No weight gain seen in the overall patient population a key benefit for people with diabetes***

**Basel, August 17, 2006** Novartis announced today that it has submitted Galvus®* (vildagliptin) for European approval for the treatment of type 2 diabetes. Galvus is a new, once-daily oral therapy that has demonstrated impressive blood sugar lowering effects, even among difficult-to-treat patients who have poor glycemic control, are obese or older than 65(1).

Galvus works through a novel mechanism of action targeting the pancreatic islet dysfunction that causes high blood sugar levels in people with type 2 diabetes(2). In clinical trials, treatment with Galvus was not associated with weight gain in the overall patient population a key benefit for people with diabetes who struggle to keep their weight under control.

Diabetes is a serious chronic disease that is growing in prevalence worldwide, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. It is impossible to overstate the urgent need for new treatments that effectively lower blood sugar levels, while being well-tolerated, particularly in terms of their impact on body weight, gastrointestinal issues and hypoglycemia. The results reported from the robust Galvus clinical trial program and included in the European filing demonstrate that Galvus may be a powerful new tool for people with diabetes.

Phase III trials for Galvus have shown significant and consistent HbA1c reductions of up to -1.8%(3) in poorly controlled patients when used as monotherapy. HbA1c is an important long-term measure of blood sugar control. Significant blood sugar reductions with Galvus have been sustained for one year(4).

Patients receiving Galvus in combination with other medicines in clinical trials were also more likely to reach their target blood sugar levels (i.e. HbA1c less than or equal to 7%)(5). In one study 65% of people reached their goal on a combination of Galvus and pioglitazone, while only 42% of patients achieved this on monotherapy on pioglitazone(5).

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* *The tradename Galvus® is currently pending regulatory, including FDA, approval*

The treatment of type 2 diabetes is still largely unsatisfactory, with an excessive proportion of patients outside the ideal goal, commented Professor Emanuele Bosi, Director of the Diabetes & Endocrinology Unit, San Raffaele University Hospital, Milan, Italy. Vildagliptin is a new drug with a novel mechanism of action, potentially able to counteract the spontaneous and progressive worsening of the disease.

He continued: The impact vildagliptin may have on diabetes treatment is potentially significant. Patients taking vildagliptin in clinical trials benefited from its ability to both stimulate insulin production and inhibit glucagon secretion, restoring a normal balance between the two that results in better blood sugar control, with a low risk of hypoglycemia and no weight gain.

**About Galvus**

Galvus is a member of the DPP-4 inhibitor class and works by targeting pancreatic islet dysfunction. In people with type 2 diabetes, this can lead to excess sugar production (via glucagon from the alpha-cells) and reduced insulin production (from the beta-cells). Galvus affects both pancreatic alpha and beta cells, improving their ability to appropriately sense and respond to sugar in the blood.

Galvus is suitable for once-daily dosing and has been evaluated both as monotherapy and in combination with other anti-diabetes agents. The effect on weight is important for many people with diabetes. In one head-to-head comparison with rosiglitazone, an insulin sensitizer, Galvus-treated patients saw a mean reduction of body weight greater than 1 kg, with an overall mean difference of 2.8 kg between the Galvus and rosiglitazone treatment groups. This weight loss was achieved with blood sugar lowering efficacy comparable to rosiglitazone(3).

The overall incidence of side effects with Galvus, including hypoglycemia (excessively low blood sugar), gastrointestinal intolerance and edema (fluid retention), was similar to placebo in monotherapy trials. The most common side effects seen in the Galvus clinical program were cold/flu-like symptoms, headaches and dizziness.

The Galvus EU regulatory submission is based on a robust clinical development program containing data from more than 5,400 patients. Galvus was accepted for US regulatory review in March 2006.

**About diabetes**

Diabetes currently affects about 230 million people worldwide and this number is estimated to grow to more than 350 million by 2025, according to the International Diabetes Federation(6). In Europe 48 million people are affected, a figure anticipated to increase to 57.6 million by 2025. Diabetes is the most common non-communicable disease, and is the fourth leading cause of death(6). In Europe, type 2 diabetes accounts for 85-95% of all diabetes cases(6).

Type 2 diabetes is a progressive disease, where control of blood sugar deteriorates over time. Diabetes can lead to heart and kidney disease, blindness, and vascular or neurological problems that can result in amputation(7).

Islet dysfunction and the body s resistance to insulin both contribute to diabetes. Specifically, islet dysfunction can lead to excess sugar production and reduced insulin production. Even among people receiving diabetes care, controlling blood sugar levels is difficult. More than half of those currently taking medication to manage their diabetes are still not reaching their blood sugar goals, according to data from the US National Health and Nutrition Examination Survey (NHANES)(8).

**Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as seeks , may be , potentially , may have , can lead , estimated to grow , anticipated to increase , or similar expression, or by express or implied discuss regarding potential future regulatory approvals or potential future sales of Galvus. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause 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 Galvus will be approved by any health authorities for sale in any market, or that Galvus will reach any particular level of sales. In particular, management s expectations regarding the approval and commercialization of Galvus could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; competition in general; unexpected clinical trial results, including additional analysis of clinical data or new clinical data; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry, and general public pricing pressures; as well as the additional 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, 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 97,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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(2). Data on file, Novartis Pharma AG.

**(3).** J. Rosenstock, M. Baron, A. Schweizer, D. Mills, S. Dejager**. (2006, June).*Galvus is as Effective as Rosiglitazone in Lowering HbA1c but without Weight Gain in Drug-Naive Patients with Type 2 Diabetes (T2DM).* Paper presented at the meeting of the American Diabetes Association, Washington, DC.**

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(8). Saydah SH, Fradkin J, Cowie CC. Poor Control of Risk Factors for Vascular Disease Among Adults with Previously Diagnosed Diabetes. *JAMA* 2004; 291(3):335-342.

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**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: August 17, 2006

By: /s/ MALCOLM B. CHEETHAM

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