NOVARTIS AG
Form 6-K
September 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 September 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

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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

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- Investor Relations Release -

Glivec® receives additional EU approvals for use in treating a rapidly progressive form of leukemia and a hard-to-treat solid cancer tumor

- *Glivec in combination with standard chemotherapy shown to restore normal blood count in 96% of patients with Ph+ acute lymphoblastic leukemia (ALL)*

- *Dermatofibrosarcoma protuberans (DFSP) represents the second approval for Glivec as treatment for a solid tumor*

- *Approvals provide new therapy for patients with few, if any, satisfactory treatment options and highlights Novartis commitment to helping patients with rare diseases*

Basel, September 19, 2006 Novartis has received additional European Union approvals for Glivec® (imatinib)*(1) to help patients with a rapidly progressive form of leukemia as well as a hard-to-treat solid cancer tumor. Both are rare and potentially life-threatening diseases with few, if any, approved treatments that have resulted in poor long-term outcomes.

Glivec, which was initially approval for treatment of patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML), has now received approval for use in adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL.

Ph+ ALL is a rapidly progressive blood cancer characterized by the presence of the Philadelphia chromosome. As in other leukemias, patients with Ph+ ALL have abnormal white blood cells (lymphocytes) that crowd out healthy white and red blood cells and platelets, leading to infection, anemia (fatigue), easy bleeding and other serious effects. The incidence of Ph+ ALL is approximately 1 to 4.75 cases per 100,000 people worldwide.

Glivec was also approved for treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. DFSP begins as a hard lump found in the skin of the chest, abdomen or leg, and progresses to invade nearby tissues. Incidence is estimated at 0.45 cases per 100,000 people annually.

Understanding the targets against which Glivec works has led to the unique opportunity to treat two rare diseases that have Glivec-sensitive pathways, said David Epstein, President of Novartis Oncology. These two new indications underscore how cancers and diseases of different origin and location share common molecular characteristics that can often respond to the same targeted treatment.

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*(1) * Known as Gleevec® (imatinib mesylate) tablets in the US*

Submissions in the EU for three other rare diseases hypereosinophilic syndrome (HES), systemic mastocytosis (SM) and myelodysplastic/myeloproliferative diseases (MDS/MPD) remain under review by the Committee for Medicinal Products for Human Use (CHMP). The US Food and Drug Administration (FDA) is also reviewing applications for approval of Glivec as a treatment for all of these five diseases.

Glivec targets the activity of abnormal proteins called tyrosine kinases that play important roles within certain cancer cells. Glivec inhibits the function of a tyrosine kinase known as Bcr-Abl in Ph+ ALL and Ph+ CML, as well as the receptor tyrosine kinase Kit in Kit (CD117)-positive GIST. Researchers have found that Glivec also inhibits other tyrosine kinases, including platelet-derived growth factor receptors (PDGFR), which have been shown to be activated in disease pathways that underlie a number of rare hematologic diseases, as well as some solid tumors. With these approvals, Glivec is now indicated to treat four distinct types of cancer shown to be sensitive to the drug s molecular targets.

About Glivec

In addition to the two new indications, Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ chronic myeloid leukemia (CML). Glivec is also approved in the EU, US and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GISTs), which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In Japan, Glivec is approved for the treatment of patients with Kit (CD117)-positive GISTs.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, and on objective response rates in GIST and DFSP. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events°(2)

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia. Glivec was generally well tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubimaemia observed when Glivec was combined with high dose chemotherapy.

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as opportunity, can often respond, or similar expressions, or by express or implied discussions regarding potential future regulatory approvals of Glivec for additional indications, or in additional markets, potential future sales of Glivec, or regarding the long-term impact of a patient s use of Glivec. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec will be approved for any additional indications in any additional markets. Neither can there be any guarantee that Glivec will achieve any

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(2) ° Numbers indicate the range in percentages in four studies among patients with CML in blast crisis, accelerated phase and chronic phase

particular levels of sales. Nor can there be any guarantee regarding the long-term impact of a patient s use of Glivec. In particular, management s expectations regarding Glivec could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including new clinical data, and additional analysis of existing clinical data; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and other risks and factors referred to in the Company 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 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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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 19, 2006

By: /s/ MALCOLM B. CHEETHAM

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