NOVARTIS AG
Form 6-K
May 11, 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 May 10, 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: ý 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**: ý

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Yes: o **No**: ý

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**: ý

Investor Relations

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- Investor Relations Release -

Five years after approval, Glivec underscores the promise of targeted therapy to provide sustained disease control

Unprecedented outcomes in Ph+ chronic myeloid leukemia (CML) patients validate the targeting of a specific cancer cause to create effective and well-tolerated therapies

First to show reduced annual progression rate with long-term use in newly diagnosed CML patients less than 1% progress to more advanced stages in fourth treatment year

New data from largest CML study ever conducted with Glivec to be presented at ASCO

Nearly 15,500 patients in more than 80 countries have received Glivec through patient assistance program

Basel, May 10, 2006 Marking an important five-year milestone since its first approval in May 2001, Gleevec/Glivec® (imatinib) has become the first oncology drug to be validated as an effective and generally well-tolerated medicine that targets a specific cause of a cancer.

Glivec was first approved in May 2001 by the US Food and Drug Administration (FDA) in an unprecedented 11 weeks the fastest FDA review period of any cancer drug at that time as a treatment for patients with advanced stage Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML).

Recent data marking 4.5 years of use showed that more than 90% of patients taking Glivec continued to survive and were free from progressing to advanced disease. A five-year update from the IRIS study (International Randomized Interferon versus STI571), the largest clinical trial to date for newly diagnosed adult patients with Ph+ CML, will be presented at

the American Society of Clinical Oncology meeting on June 3.

Before Glivec was available, about 50% of patients with this disease progressed to the more advanced stages of Ph+ CML after only three to five years and survival was generally short for those patients. Traditional, less-targeted treatments were associated with significant toxicities that often limited the ability of patients to stay on therapy long-term.

Glivec has an unprecedented record of efficacy and safety for the treatment of patients suffering from chronic myeloid leukemia, allowing many to resume their daily lives said Dr. Daniel Vasella, Chairman and CEO of Novartis. After more than a decade of research and clinical development as well as over 200,000 patient years of clinical treatment, we are moving forward with confidence in the principles of rational drug design pioneered with Glivec. The success of Glivec gives us confidence in the search for novel medicines that offer improved treatment outcomes.

No other drug for this disease has ever established such a proven and durable track record of efficacy and safety. Interim 54-month data from the IRIS study showed that approximately 93% of newly diagnosed patients with Ph+ CML treated with Glivec had not progressed to the more advanced and terminal stages.

What Glivec tells us is that a precise understanding of what drives the growth of a particular cancer allows us to target those abnormalities specifically and develop an effective, durable and well-tolerated treatment, said Brian Druker, MD, JELD-WEN Chair of Leukemia Research at the Oregon Health and Science University Cancer Institute, Howard Hughes Medical Investigator and lead investigator of the key Glivec clinical trials. After five years, we know with certainty that going after the root cause of a cancer, and shutting it down, not only makes sense it works.

Glivec is the first targeted therapy for patients with Ph+ CML since it has been proven to inhibit Bcr-Abl, the definitive cause of the disease. Following the rapid US approval on May 10, 2001, Glivec was approved later that year in the European Union and subsequently in other countries worldwide. Glivec has also been approved in the meantime for all phases of Ph+ CML.

After initial approval, Novartis led the industry in creating the Glivec International Patient Assistance Program (GIPAP). Nearly 15,500 patients in more than 80 countries have received Glivec under GIPAP and in the United States under the US Patient Assistance Program. These programs provide Glivec, in accordance with the drug s specific approved use in countries, at no cost to qualified patients who are properly diagnosed, not insured, not reimbursed and have no other financial resource.

Novartis has continued to investigate Glivec for use in treating patients with other types of cancer. In 2002, Glivec was approved worldwide for the treatment of patients with unresectable and/or metastatic Kit (CD117)-positive gastrointestinal stromal tumors (GISTs).

In 2005, Glivec was also submitted in the US and EU as a treatment for the solid tumor dermatofibrosarcoma protuberans and certain forms of myeloproliferative disorders as well as for the treatment of adult patients with Ph+ acute lymphoblastic leukemia (ALL). This year, Novartis submitted additional applications for the use of Glivec in treating two rare hematologic malignancies: hypereosinophilic syndrome and systemic mastocytosis. All five of these diseases are considered rare but may be life threatening and often have no approved treatments.

About Glivec

Gleevec/Glivec (imatinib) is a signal transduction inhibitor approved to treat certain forms of leukemia and gastrointestinal stromal tumors. It is one of the first oncology drugs that validates rational drug design based on an understanding of how some cancer cells work. A signal transduction inhibitor interferes with the pathways that stimulate the growth of tumor cells.

Glivec is indicated in the EU for the treatment of patients with newly diagnosed Ph+ CML for whom bone marrow transplantation is not considered as the first line of treatment. Glivec/Gleevec is approved in the US for newly diagnosed adult patients with Ph+ chronic phase CML and pediatric patients with Ph+ chronic phase CML whose disease has recurred after stem cell (an unspecialized cell that gives rise to differentiated cells) transplant or who are resistant to interferon-alpha treatment. In Japan, Glivec is approved for adult patients in all phases of Ph+ CML. In addition, Glivec is already approved for the treatment of adult patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha treatment in more than 90 countries worldwide.

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 and objective response rates in GIST. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events*

The most common undesirable effects experienced during Glivec treatment in GIST are: headache, nausea, vomiting, diarrhea, dyspepsia, myalgia, muscle spasm and cramps, joint swelling, dermatitis, eczema, rash, edema, fluid retention, neutropenia, thrombocytopenia or anemia. In the first-line study (IRIS), the safety profile with Glivec was similar to that of previous Phase II studies in other CML patients. The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. 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 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.

* Numbers indicate the range in percentages in four studies among patients with CML in blast crisis, accelerated phase and chronic phase

The foregoing release contains forward-looking statements that can be identified by terminology such as will , are moving forward with confidence , or similar expressions, or by express or implied discussions regarding potential new indications for Glivec or potential future sales 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 market. Nor can there be any guarantee regarding potential future sales of Glivec. In particular, management s expectations regarding commercialization of Glivec could be affected by, among other things, additional analysis of Glivec clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; 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, 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 91,000 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: May 10, 2006

By: /s/ MALCOLM B. CHEETHAM

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