NOVARTIS AG
Form 6-K
September 22, 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 21, 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 Global Communications
CH-4002 Basel
Switzerland
hppt://www.novartis.com

- Investor Relations Release -

EMBARGOED UNTIL THURSDAY 21 SEPTEMBER AT 7:15 am CET

Sebivo® receives first major approval in Switzerland as new treatment for patients with chronic hepatitis B

- *Swiss approval supports global regulatory submissions in over 100 other countries to make Sebivo available to the 350 million chronic hepatitis B patients worldwide*

- *Sebivo suppresses hepatitis B virus more rapidly and profoundly than lamivudine*

- *Approval based on data from the GLOBE study, the largest worldwide registration trial ever conducted in patients with chronic hepatitis B*

Basel, September 21, 2006 Sebivo® (telbivudine), a new treatment for patients with chronic hepatitis B shown to deliver more rapid and profound viral suppression than lamivudine, has received approval in Switzerland.

This important approval provides access to an innovative new therapy for Swiss patients but also supports expanded regulatory submissions. More than 100 countries worldwide look to the approval of a medicine in the company s home country to serve as a reference for local regulatory reviews.

A single pill taken orally once daily with or without food, Sebivo has been shown to effectively suppress replication of the hepatitis B virus(1).

Approximately 350 million people worldwide are living with chronic hepatitis B(2), a virus that affects the liver and is estimated to be 50 to 100 times more infectious than human immunodeficiency virus (HIV)(2). Hepatitis B virus can cause chronic lifelong infection, which can lead to several liver conditions including cirrhosis (scarring), cancer or organ failure and death(3). Hepatitis B is the second most common cause of cancer after smoking(2), with 1.2 million people estimated to die annually from hepatitis B-related chronic liver disease(4).

We are committed to helping physicians offer better care for patients with chronic hepatitis B, and the approval of Sebivo in Switzerland is a significant step toward achieving this goal, said Giacomo di Nepi, Head of the Infectious Diseases, Transplantation and Immunology Business Unit at Novartis Pharma AG. This approval not only makes Sebivo available in Switzerland but also supports approvals in many countries that first require Swiss approval.

Applications for approval were filed with the US Food and Drug Administration (FDA) in late 2005 as well as with the European Medicines Agency (EMEA) and the Chinese health authority in the first quarter of 2006. A different trademark for telbivudine in the US is currently under discussion.

About the GLOBE study

The approval of Sebivo is based primarily on one-year data from the GLOBE study, the largest worldwide registration trial ever conducted in patients with chronic hepatitis B. This two-year Phase III clinical trial compared Sebivo with lamivudine in the treatment of 1,367 adults with chronic hepatitis B at 112 clinical centers in 20 countries(1).

Results from GLOBE indicate that Sebivo produces significantly greater viral suppression on a number of virologic markers compared to lamivudine after one year in both chronic hepatitis B e-antigen (HBeAg) positive and negative patients. Two-year data from the GLOBE study is planned to be presented at the American Association for the Study of Liver Disease meeting in Boston on October 30.

The goal of managing chronic hepatitis B is to prevent long-term complications such as liver damage or liver cancer, which is possible through rapid, profound and sustained suppression of the hepatitis B virus, said Professor Rafael Esteban, Head of Internal Medicine and Chief of the Liver Unit at the Hospital Universitario Vall d Hebron in Barcelona, Spain. Telbivudine s demonstrated ability to drive down virus levels in the first six months of treatment, along with its favorable safety and convenience profile in clinical trials to date, make it a promising treatment option for patients.

The primary efficacy endpoint of the GLOBE study was therapeutic response at one year, a composite endpoint coupling viral suppression (serum HBV DNA suppression below 100,000 copies/mL) with either improved liver disease markers (ALT normalization) or loss of detectable hepatitis B e-antigen (HBeAg). In HBeAg-positive patients, therapeutic response was significantly higher among patients treated with Sebivo compared to those treated with lamivudine (75 vs. 67 percent respectively, $p<0.05$), while the response after one year was similar for HBeAg-negative patients taking either treatment (75 vs. 77 percent respectively).

Patients receiving Sebivo showed significantly less viral resistance and less treatment failure, compared to patients receiving lamivudine at one year. Sebivo was associated with significantly fewer and less severe elevations (flares) of serum ALT levels, a potential cause of liver failure in chronic hepatitis B patients, compared to lamivudine. Grade 3-4 creatine kinase (CK) elevations were more common with Sebivo than lamivudine (7.5 versus 3.1 percent, respectively). The 52-week GLOBE study results support a favorable overall safety profile for Sebivo. The type and rate of occurrence of adverse events were similar between Sebivo-treated patients and lamivudine-treated patients.

Idenix/Novartis collaboration

Sebivo is being developed in collaboration between Idenix Pharmaceuticals, Inc. and Novartis Pharma AG under a development and commercialization arrangement established in May 2003, along with another hepatitis B clinical product candidate, valtorcitabine.

The collaboration arrangement further provides that Idenix and Novartis will co-promote Sebivo and valtorcitabine and other product candidates that Novartis has licensed, upon successful development and approval, in the US, France, Germany, Italy, Spain and the UK.

Novartis holds the exclusive license to commercialize Sebivo and valtorcitabine in the rest of the world. In March 2006, Novartis expanded its collaboration with Idenix to include valopicitabine for the treatment of chronic hepatitis C.

Disclaimer

This release contains certain forward-looking statements , relating to Novartis business, which can be identified by the use of forward-looking terminology such as estimated , committed , planned, goal , promising , or similar expressions, or by express or implied discussions regarding potential approval of Sebivo by additional regulatory authorities, or regarding potential future sales of Sebivo. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Sebivo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Sebivo will be approved for sale in any additional markets, or that it will reach any particular level of revenue. Novartis expectations regarding Sebivo could be affected by, among other things, unexpected regulatory actions or delays or government

regulation generally; uncertainties relating to clinical trials, including new clinical data and additional analysis of existing clinical data; Novartis and Idenix s ability to obtain or maintain patent or other proprietary intellectual property protection; Idenix s dependence on its collaboration with Novartis Pharma AG; Idenix s ability to obtain additional funding required to conduct its research, development and commercialization activities; competition in general; government, industry, and general public pricing pressures; as well as other risks and factors referred to in Novartis 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 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 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.

References

(1) Lai C. Hepatology. 2005 Oct (42, S1): 748A.

(2) Lavanchy D. J Viral Hepat. 2004 Mar 11 (2): 97-107

(3) CDC Frequently Asked Questions. Available at: www.cdc.gov/ncidod/diseases/hepatitis/b/faqb.htm

(4) World Health Organization. Hepatitis B. Available at: http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index1.html.

# # #

Media contacts

Corinne Hoff

Novartis Global Media Relations

+41 61 324 9577 (direct)

+41 79 248 5717 (mobile)

corinne.hoff@novartis.com

Birgit Gronkowski

Novartis Pharma Communications

+41 61 324 8790 (direct)

+41 79 820 1719 (mobile)

birgit.gronkowski@novartis.com

Novartis Global Investor Relations

International:

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

North America:

Ronen Tamir +1 212 830 24 33
Arun Nadiga +1 212 830 24 44
Jill Pozarek +1 212 830 24 45
Edwin Valeriano +1 212 830 24 56
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: September 21, 2006

By: /s/ MALCOLM B. CHEETHAM

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