NOVARTIS AG
Form 6-K
October 26, 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 October 26, 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):

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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 -

Tyzeka(TM) receives US regulatory approval as a new treatment for patients with chronic hepatitis B

- *An estimated 1.25 million Americans currently infected with chronic hepatitis B1*
- *Clinical data demonstrate Tyzeka (telbivudine) achieves early and profound viral suppression of the hepatitis B virus*
- A*lready available in Switzerland, telbivudine to be marketed as Sebivo® outside the US*

Basel, October 25, 2006 - Novartis announced today the US regulatory approval of Tyzeka(TM) (telbivudine) as a new once-a-day oral treatment for patients with chronic hepatitis B, a disease estimated to affect about 1.25 million people in the US but more than 350 million globally and considered the tenth leading cause of death.

Taken with or without food, Tyzeka suppresses the hepatitis B virus (HBV) rapidly and profoundly in adult patients with evidence of viral replication and evidence of either persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Already available in Switzerland, and now approved by the US Food and Drug Administration, telbivudine will be marketed as Sebivo® outside the US. It has also been submitted for regulatory approval with the European Medicines Agency (EMEA) and the Chinese health authority in the first quarter of 2006.

Profound suppression of the hepatitis B virus is associated with improved outcomes and is a primary treatment goal, said Dr. Adrian M. Di Bisceglie, MD, Professor of Medicine and Chief of Hepatology, Division of Gastroenterology and Hepatology, at St. Louis University, and Co-director, St. Louis University Liver Center, US.

Tyzeka s ability to provide rapid viral suppression in the first 24 weeks of treatment, along with its demonstrated safety and tolerability profile, make it a promising treatment option for patients, Dr. Di Bisceglie said.

Approximately 1.25 million people in the US are living with chronic hepatitis B, a virus that infects the liver and is 50 to 100 times more infectious than HIV(1). Chronic hepatitis B is estimated to

affect approximately 350 million people worldwide(1) and is the tenth leading cause of death worldwide, responsible for up to 1.2 million deaths each year(2).

Novartis is committed to infectious diseases and the development of new therapies in the treatment of hepatitis, said Giacomo di Nepi, Head of Infectious Diseases, Transplantation and Immunology at Novartis Pharma AG. The approval of Tyzeka demonstrates our dedication to provide additional treatment options to patients with chronic hepatitis B and physicians.

About the GLOBE study

The US approval was based primarily on one-year results from the GLOBE study, the largest worldwide registration trial ever conducted in patients with chronic hepatitis B. 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 75 vs. 67 percent among patients treated with Tyzeka compared to those treated with lamivudine, while the response after one year was 75 vs. 77 percent, respectively, for HBeAg-negative patients taking either treatment. In the phase III registration trial, the majority of Tyzeka-treated patients achieved undetectable levels of virus in the first 24 weeks of treatment, and in 95 percent of those patients the virus remained undetectable at one year.

Patients receiving Tyzeka showed significantly less viral resistance and less treatment failure compared to patients receiving lamivudine at one year. Tyzeka 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 Tyzeka than lamivudine (7.5 versus 3.1 percent, respectively).

The 52-week GLOBE study results support a favorable overall safety profile for Tyzeka. The type and rate of occurrence of adverse events were similar between Tyzeka-treated patients and lamivudine-treated patients.

Tyzeka has a Category B pregnancy rating. There are no adequate and well-controlled studies of telbivudine in pregnant women. Because animal reproductive toxicity studies are not always predictive of human response, telbivudine should be used during pregnancy only if potential benefits outweigh the risks.

Idenix/Novartis collaboration

Tyzeka is being developed in collaboration between Idenix and Novartis Pharma AG under a development and commercialization arrangement established in May 2003. Idenix is also developing valtorcitabine, another hepatitis B compound, and valopicitabine, a hepatitis C compound, in collaboration with Novartis. Under this agreement, Novartis and Idenix will co-promote telbivudine, valtorcitabine and valopicitabine in the United States, France, Germany, Italy, Spain and the United Kingdom. Novartis has the exclusive right to commercialize telbivudine, valtorcitabine and valopicitabine in the rest of the world.

Novartis is committed to infectious diseases and is developing a portfolio of complementary mechanisms of action in the treatment of hepatitis B and C, while working to bring innovation for serious hospital infections.

Disclaimer

This release contains certain forward-looking statements , relating to the Group s business, which can be identified by the use of forward-looking terminology such as to be marketed , will , promising, committed to , dedication to , potential , or similar expressions, or by express or impl discussions regarding potential approvals of Tyzeka in additional markets, or potential future revenues from Tyzeka. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Tyzeka to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tyzeka will be approved for sale in any additional markets, or that it will reach any particular levels of revenue. Management s expectations regarding Tyzeka 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; competition in general; government, industry, and general public pricing pressures; the company 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; as well as 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 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 99,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

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

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

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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: October 26, 2006	By:	/s/	MALCOLM B. CHEETHAM
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	Title:		Head Group Financial Reporting and Accounting