

NOVARTIS AG
Form 6-K
August 13, 2007

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 10, 2007

(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: Form 40-F:

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: No:

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: No:

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: No:

Novartis International AG

Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

FDA grants additional six months marketing exclusivity for the high blood pressure medicine Diovan®

- *Exclusivity based on pediatric high blood pressure program*
- *FDA priority review of Diovan high blood pressure indication in children and adolescents expected to be completed by end 2007*
- *Nearly 5% of children and adolescents in the US may have high blood pressure⁽¹⁾*

Basel, August 10, 2007 Diovan® (valsartan) has been granted pediatric exclusivity by the US Food and Drug Administration (FDA) based on studies conducted in children with high blood pressure. This action extends marketing exclusivity associated with the valsartan compound patent by six months from March to September 2012.

Although high blood pressure is more prevalent in adults, affecting 30% of Americans⁽²⁾, it has been reported that nearly 5% of children and adolescents in the US may have the condition⁽¹⁾. An FDA decision on a possible indication to treat children and adolescents with high blood pressure is anticipated by the end of 2007.

Novartis feels that wherever possible it is important to ensure that medications are studied in patient groups usually excluded from general clinical trials, such as younger people, said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

Diovan is the only agent in its class (angiotensin receptor blocker or ARB) indicated to treat not only adults with high blood pressure, but also those with heart failure and heart attack survivors.

The need for high blood pressure medicines is strong given that the condition affects approximately 72 million adult Americans⁽²⁾ and nearly a billion people worldwide⁽³⁾. Of those who are being treated, more than 40% do not have the condition controlled⁽⁴⁾. Uncontrolled high blood pressure has been shown in adults to increase the risk of heart attack and stroke, which are among the world's leading causes of death⁽⁵⁾.

The benefits of Diovan have been demonstrated through the Diovan clinical trials program involving more than 50,000 patients. The megatrials VALUE, VALIANT, and Val-HEFT demonstrated the unsurpassed blood pressure-lowering efficacy and cardioprotective benefits of Diovan in a range of different patient types^{(6),(7),(8)}. Diovan is available as a powerful first-line treatment for high blood pressure in more than 100 countries, for the treatment of people with heart failure in more than 90 countries, and for the treatment of heart attack survivors in more than 70 countries.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, may, possible, anticipated, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Diovan or regarding potential future revenues from Diovan. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Diovan will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Diovan could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected 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 Novartis AG'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, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) Sorof J, Lai D, Turner J et al. Overweight, ethnicity, and the prevalence of hypertension in school-aged children. *Pediatrics*. 2004;113:475-482.
- (2) Heart Disease and Stroke Statistics 2007 Update. *Circulation* online Dec 28, 2006; DOI: 10.1161/CIRCULATIONAHA.106.179918.
- (3) Kearney et al. Global burden of hypertension: analysis of worldwide data. *Lancet* 2005; 365: 217-223
- (4) Ong KL, Cheung BMY, Man YB, et al. Prevalence, awareness, treatment, and control of hypertension among United States adults 1999-2004. *Hypertension*. 2007;49:69-75.
- (5) The World Health Organization. *The World Health Report 2002: Reducing Risk, Promoting Healthy Life*. 2002.
- (6) Julius S et al. Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. *Lancet* 2004; 363: 2022-31.
- (7) Pfeffer MA et al. Valsartan, captopril, or both in myocardial infarction complicated by heart failure, left ventricular dysfunction, or both. *N Engl J Med*. 2003; 349(20): 1893-906.
- (8) Cohn J et al. A randomized trial of the angiotensin-receptor-blocker valsartan in chronic heart failure. *N Engl J Med*. 2001; 345: 1667-1675.

###

Novartis Media Relations

Corinne Hoff

Novartis Global Media Relations
+41 61 324 9577 (direct)
+41 79 248 5717 (mobile)
corinne.hoff@novartis.com

Vivienne Schneider

Novartis Pharma Communications
+41 61 324 6162 (direct)
+41 79 619 1335 (mobile)
vivienne.schneider@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International

Ruth Metzler-Arnold

Katharina Ambuehl
Nafida Bendali
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis

North America

Ronen Tamir

Jill Pozarek
Edwin Valeriano

+1 212 830 2433
+1 212 830 2445
+1 212 830 2456

Central phone no: +41 61 324 7944

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: August 10, 2007

By: /s/ MALCOLM B. CHEETHAM

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