

NOVARTIS AG
Form 6-K
September 06, 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 3, 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: ☒ **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:** ☒

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- Investor Relations Release -

New Rasilez® data highlight potential of direct renin inhibition to control blood pressure over long-term without risk of rebound(1)

- *As monotherapy or combination therapy, once-daily Rasilez provides consistent and sustained blood pressure lowering over one year of treatment(1)*
- *Rasilez provides sustained 24-hour blood pressure control, with no rebound high blood pressure seen after discontinuation of therapy(1)*
- *Direct renin inhibitors expected to be the first new class of high blood pressure medicines available in more than 10 years*

Basel, September 3, 2006 - Novartis announced today new data showing that its direct renin inhibitor Rasilez® (aliskiren) demonstrates long-term and sustained blood pressure control without risk of rebound high blood pressure(1). The data were presented by investigators at the 15th World Congress of Cardiology in Barcelona, Spain.

These data add to the growing body of evidence that suggest direct renin inhibition is an effective means of controlling high blood pressure(2). As a direct renin inhibitor, Rasilez would represent the first new treatment approach for high blood pressure in more than a decade.

The clinical trial results presented today highlight the power of Rasilez to maintain its blood pressure lowering effect over one year of therapy. Patients in the study taking Rasilez alone or in combination with diuretic hydrochlorothiazide lowered their blood pressure substantially (-17.4/-13.3 mmHg and -18.7/-12.1 mmHg, respectively).

These reductions were sustained over 24 hours(1) - an important treatment consideration because many high blood pressure medicines fail to provide 24-hour control. True 24-hour blood pressure control can reduce the risk of heart attacks and strokes(3).

Interestingly, the study investigators also concluded that people in the study taking Rasilez avoided rebound high blood pressure, a potentially dangerous condition(1),(4). After 11 months on Rasilez, some patients were switched to placebo. Despite this switch, their blood pressures rose only gradually toward baseline over the following month with no evidence of rebound(1).

Normally we'd expect blood pressure to quickly return to pre-treatment levels when a medicine is stopped, said Dr. Domenic Sica, Professor of Medicine and Pharmacology at the Medical College of Virginia Commonwealth University in Richmond, Virginia. However, our study showed

that this does not occur with aliskiren. This may be a benefit of directly inhibiting renin to control blood pressure.

Throughout the clinical program including this trial, Rasilez has consistently shown tolerability comparable to placebo at doses up to 300 mg daily (i.e. within the expected therapeutic dose range). Rasilez has also been well-tolerated when used alone or with other common cardiovascular and anti-diabetic medicines(2).

About Rasilez

Rasilez, which was developed in collaboration with Speedel, acts within the renin system that is central to blood pressure regulation. By directly inhibiting the renin system's point of activation - renin - Rasilez decreases the system's activity, as measured by plasma renin activity (PRA)(2).

The US submission of Rasilez was completed in April 2006, while the European submission is expected before for the end of 2006.

About high blood pressure

High blood pressure - and its consequences - is the world's no. 1 killer and is estimated by the American Heart Association to affect one in four adults, which totals nearly one billion people globally(5),(6). Despite extensive use of current therapies, about 70% of all people with high blood pressure do not reach target blood pressure levels. Many people require three or more medicines to control their blood pressure(7). Meanwhile, many existing treatments fail to provide sustained 24-hour blood pressure control, particularly during the early morning hours(3).

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as potential, expected to be, would represent, may be, suggest, or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Rasilez. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Rasilez will be approved for sale in any market, or that it will reach any particular sales levels. In particular, management's expectations regarding the approval and commercialization of Rasilez could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; 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; increased 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, 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) Sica, et al. Aliskiren, a novel renin inhibitor, is well tolerated and has sustained BP-lowering effects alone or in combination with HCTZ during long-term (52 weeks) treatment of hypertension. Poster presented at the 15th World Congress of Cardiology 2006.
- (2) Rasilez data on file at Novartis
- (3) Body Rhythm Hypertension High Blood Pressure. MedicineNet.com. Available at: <http://www.medicinenet.com/script/main/art.asp?articlekey=875> Accessed on 13/07/06
- (4) Drug Induced Hypertension. MedlinePlus Medical Encyclopedia. Available at: <http://www.nlm.nih.gov/medlineplus/ency/article/000155.htm> Accessed on 13/07/06.
- (5) Review of Clinical Hypertension. American Society of Hypertension. 2005
- (6) JNC-7, The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *JAMA* 2003.
- (7) Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States, 1988-2000. *Journal of the American Medical Association*. 9 July 2003: 202.

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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 3, 2006

By: /s/ MALCOLM B. CHEETHAM
Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting