

NOVARTIS AG  
Form 6-K  
July 29, 2008

# 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 July 28, 2008**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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**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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**Novartis International AG**  
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**-Investor Relations Release-**

**Exforge® helps nearly twice as many patients control their high blood pressure compared to amlodipine alone**

- *New data show that patients on Exforge with baseline blood pressure  $\geq 180$  mmHg experienced significant reductions of up to 40 mmHg to help reach target levels(1)*
- *Significant blood pressure reductions seen with Exforge across difficult-to-treat groups such as the elderly, obese and people with diabetes(1)*
- *High blood pressure is a leading but treatable risk factor for cardiovascular disease the world's leading cause of death(2)*

**Basel, July 28, 2008** New data show that Exforge, a single-pill combination of the world's leading high blood pressure medicines Diovan® (valsartan) and amlodipine, gets nearly twice as many patients with high baseline blood pressure to a healthier blood pressure goal compared to amlodipine alone(1).

Results of a study in patients with systolic baseline blood pressure  $\geq 160$  mmHg, published in *The Journal of the American Society of Hypertension*, showed that 51.8% of patients on Exforge achieved systolic blood pressure control defined as  $< 140$  mmHg at week four, compared to 27.7% of those on amlodipine alone(1). Systolic blood pressure, measured when the heart contracts and pumps, is an important indicator of a person's risk of cardiovascular events(3).

The blood pressure drops achieved with Exforge are important since systolic blood pressure continues to increase with age. Therefore as population demographics shift towards older age, the cardiovascular disease burden could almost be entirely attributable to systolic blood pressure, said Dr. Maurizio Destro, lead investigator from the Azienda Ospedaliera di Pavia in Italy. Furthermore, 65% of people with high blood pressure do not achieve their blood pressure goal, and most require two or more medicines. Patients are more likely to keep taking a single pill a day rather than multiple medications, so Exforge is clearly an important and effective therapy option.

The primary endpoint of the study was the change from baseline Mean Sitting Systolic Blood Pressure (MSSBP) at week four. Results showed that on average, patients on Exforge experienced a significant 30.1 mmHg reduction in systolic blood pressure compared to a 23.5 mmHg reduction in patients on amlodipine alone(1).

In the same study, patients with systolic blood pressure  $\geq 180$  mmHg treated with Exforge experienced significant systolic blood pressure reduction of up to 40.1 mmHg, compared with 31.7 mmHg for those treated with amlodipine alone(1).

Exforge also demonstrated significantly better blood pressure-lowering efficacy than amlodipine alone across certain difficult-to-treat patient groups, including the elderly (over 65 years), obese people and those with diabetes(1).

Treatment guidelines recommend that patients with high blood pressure  $\geq 160/100$  mmHg should be considered for a combination of two medicines from different drug classes(4).

To lower the risk of complications from uncontrolled high blood pressure, it is vital to treat patients early and effectively, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Exforge consistently demonstrates large blood pressure drops across all stages of high blood pressure and has been shown to get as many as nine out of 10 patients without diabetes to goal.

High blood pressure is a leading cause of cardiovascular disease, the world's number one cause of death(2). Controlling high blood pressure can reduce complications such as heart attack, heart failure, stroke, kidney failure and premature death(3).

The study was designed to investigate and compare the efficacy and safety of Exforge with amlodipine in patients with stage 2 high blood pressure (a more severe stage of the disease, with systolic blood pressure between 160 and 200 mmHg). It was a randomized, double-blind, multi-center parallel-group study carried out in 75 centers across Europe and the US. In total, 646 patients were randomized to receive treatment with Exforge 5-10/160 mg (n=322) or amlodipine 5-10 mg (n=324). Demographic and high blood pressure baseline characteristics were similar for both groups(1).

Overall blood pressure measurements consist of two values, both expressed in millimeters of mercury (mmHg). The first is the systolic blood pressure when the heart beats and the second is the diastolic pressure when the heart relaxes between beats. In this study, overall blood pressure control rates ( $<140/90$  mmHg) were higher at all assessment points for patients treated with Exforge than for those receiving amlodipine alone. In this study both medications were well tolerated(1).

Novartis is focused on improving the lives of the hundreds of millions of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes – both major public health issues.

The core of the Novartis portfolio is its cardiovascular medications for the treatment of high blood pressure and diabetes. These include the world's most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients improve cardiovascular and metabolic health through effective medicines, programs and an ongoing commitment to research.

#### **Disclaimer**

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The foregoing release contains forward-looking statements that can be identified by terminology such as will, may, potential, could, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Exforge or regarding potential future revenues from Exforge. 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 Exforge to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee

that Exforge will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Exforge will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exforge 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

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- (2) Kearney et al. Global burden of hypertension: analysis of worldwide data. *The Lancet*. 2005;265:217-23
- (3) Chobanian et al. Seventh Report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Hypertension*. 2003;42:12006-1251.
- (4) Mancia G et al. The 2007 ESH/ESC Guidelines for the management of arterial hypertension. *J Hypertens* 2007;26(4):825-6.

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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: July 28, 2008

By: /s/ MALCOLM B. CHEETHAM

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