

NOVARTIS AG  
Form 6-K  
May 16, 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 May 14, 2008**

**(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:

Edgar Filing: NOVARTIS AG - Form 6-K

**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 -**

**Significant blood pressure reductions seen in difficult-to-treat, black patients receiving Exforge®-based therapy(1)**

- *Study sub-group with severe high blood pressure shows largest blood pressure drop to date in an Exforge clinical trial(2),(3),(4)*
- *After only two weeks, Exforge delivered significantly greater reductions in blood pressure than amlodipine alone(1)*
- *20 mmHg decrease in systolic blood pressure halves risk of death from heart disease or stroke(5)*

**Basel, May 14, 2008** New multinational data show that black patients treated with Exforge® experienced a significantly higher reduction in systolic blood pressure than those on amlodipine alone (33 mmHg vs. 27 mmHg,  $P < 0.0001$ )(1).

In addition, a subgroup of black patients with severe high blood pressure achieved an average systolic blood pressure reduction of 50 mmHg(1) when taking Exforge and, in some cases, additional hydrochlorothiazide (HCT) at the discretion of the investigator. This is the most significant blood pressure drop seen to date in an Exforge clinical trial(2),(3),(4).

Exforge, a combination of the world's leading high blood pressure medicines Diovan® (valsartan) and amlodipine, produced a significant decrease in blood pressure after only two weeks compared to amlodipine alone (25 mmHg vs. 19 mmHg,  $P < 0.0001$ )(1).

Uncontrolled blood pressure in difficult-to-treat patients can lead to an increased risk of heart attack and stroke(6). Studies have shown that lowering systolic blood pressure by 20 mmHg can halve the risk of heart attack and stroke(5).

The large blood pressure reductions seen in this trial were experienced by severe patients who have the most difficulty getting their blood pressure to healthy levels, said Dr. John M. Flack, the lead investigator from Wayne State University School of Medicine, Detroit. These data may have a real impact on helping patients who are most at risk.

The results, presented today at the American Society of Hypertension (ASH) 23rd Annual Scientific Meeting and Exposition in New Orleans, show that Exforge got patients in a difficult-to-treat group—black patients with systolic blood pressure  $\geq 160$  mmHg—to healthy blood pressure levels(1).

## Edgar Filing: NOVARTIS AG - Form 6-K

Black patients are at higher risk of developing high blood pressure than other ethnic groups for reasons that are not fully understood(7). They are also less likely than white patients to achieve blood pressure control while receiving treatment(7). Guidelines recommend that combination therapy

should be used as first-line treatment in difficult-to-treat patient groups(6),(8). Exforge is not currently approved as a first-line treatment for high blood pressure.

High blood pressure is a leading risk factor for cardiovascular disease – the world’s number one cause of death(9). The condition is treatable, yet 70% of people with high blood pressure are not at goal(10).

With Exforge, we have a treatment that can help many patients achieve healthy blood pressure levels, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Importantly, Exforge has been shown to be effective across all grades of high blood pressure and to get as many as nine out of 10 patients to goal. In this study, Exforge demonstrated strong blood pressure lowering efficacy in high-risk, more difficult-to-treat patient populations. Exforge provides an important and effective treatment option for physicians.

The study presented at ASH investigated whether combination therapy with Exforge is an effective choice in difficult-to-treat, black patients with stage 2 high blood pressure – a more severe stage of the disease, with systolic blood pressure between 160 and 200 mmHg(1). Systolic blood pressure, measured when the heart contracts and pumps, is the most important indicator of a person’s risk of cardiovascular events(6).

The 12-week randomized, double-blind, parallel-group study was carried out among black patients in the US, South America and South Africa. A total of 572 black patients were randomized to receive either Exforge 5-10/160 mg (n=286) or amlodipine 5-10 mg and placebo (n=286). Demographic and baseline clinical characteristics were comparable between groups(1).

The primary endpoint of the study was the change in systolic blood pressure after eight weeks. Results showed that on average, patients treated with Exforge experienced a significantly greater reduction in systolic blood pressure than those on amlodipine alone (33 mmHg vs. 27 mmHg,  $P < 0.0001$ )(1). After eight weeks, those patients with a systolic blood pressure  $\geq 130$  mmHg could have open-label HCT added at the investigator’s discretion (Exforge n=146, amlodipine n=183)(11).

At study end, the sub-group of patients with systolic blood pressure  $\geq 180$  mmHg at baseline taking Exforge, and in some cases HCT at the discretion of the investigator, achieved an average systolic blood pressure reduction of 50 mmHg (n=35), compared to an average 41 mmHg reduction in those taking amlodipine with additional HCT at the discretion of the investigator (n=40,  $P=0.047$ )(1). Both medications were well tolerated with adverse events being mild, transient and consistent with the class of agents studied(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

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, can, may, likely, should, 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and 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>.

---

## References

- (1) Flack J et al. Efficacy and Safety of Amlodipine/Valsartan Combination Therapy Compared with Amlodipine Monotherapy in Black Patients with Stage 2 Hypertension. *ASH*, 2008.
- (2) Poldermans D et al. Tolerability and Blood Pressure-Lowering Efficacy of the Combination of Amlodipine Plus Valsartan Compared with Lisinopril Plus Hydrochlorothiazide in Adult Patients with Stage 2 Hypertension. *Clinical Therapeutics*. 2007;29:1-11.
- (3) Philipp T et al. Two Multicenter, 8-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Studies Evaluating the Efficacy and Tolerability of Amlodipine and Valsartan in Combination and as Monotherapy in Adult Patients with Mild to Moderate Essential Hypertension. *Clinical Therapeutics*. 2007;29:563-580.
- (4) Smith TR et al. Amlodipine and Valsartan Combined and as Monotherapy in Stage 2, Elderly, and Black Hypertensive Patients: Subgroup Analyses of 2 Randomized, Placebo-Controlled Studies. *Journal of Clinical Hypertension*. 2007;9:355-364.
- (5) Lewington et al. Age-specific relevance of usual blood pressure to vascular mortality: a meta analysis on individual data for one million adults in 61 prospective studies. *The Lancet*. 2001;360:1903.
- (6) Chobanian AV et al. Seventh report of the Joint National Committee on prevention, detection, evaluation and treatment of high blood pressure. *Hypertension*. 2003;42:1206-1251
- (7) Hertz et al. Racial Disparities in Hypertension Prevalence, Awareness, and Management. *Arch Intern Med*. 2005;165:2098-2104.
- (8) The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). 2007 Guidelines for the Management of Arterial Hypertension. *Eur Heart J*. 2007;28:1462-1536.
- (9) Kearney et al. Global burden of hypertension: analysis of worldwide data. *The Lancet*. 2005;365:217-23





- (10) Ong et al. Prevalence, Awareness, Treatment, and Control of Hypertension Among United States Adults 1999-2004. Hypertension. 2007;49:69-75.
- (11) Flack J et al. Combination of Angiotensin-receptor blocker, Calcium-channel blocker and Diuretic is Safe and Effective in the Management of Severe Hypertension in Blacks. ASH, 2008.

###

#### Novartis Media Relations

##### **Beatrix Benz**

Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 618 7748 (mobile)  
beatrix.benz@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

##### **Ruth Metzler-Arnold**

Katharina Ambuehl +41 61 324 9980  
+41 61 324 5316  
Pierre-Michel Bringer +41 61 324 1065  
John Gilardi +41 61 324 3018  
Thomas Hungerbuehler +41 61 324 8425  
Isabella Zinck +41 61 324 7188

Central phone no: +41 61 324 7944  
Fax no: +41 61 324 8444  
e-mail: investor.relations@novartis.com

##### **North America Office**

Richard Jarvis +1 212 830 2433  
Jill Pozarek +1 212 830 2445  
Edwin Valeriano +1 212 830 2456

Fax no: +1 212 830 2405  
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: May 14, 2008

By: /s/

MALCOLM B. CHEETHAM

Name:

Malcolm B. Cheetham

Title:

Head Group Financial  
Reporting and Accounting