

NOVARTIS AG
Form 6-K
March 31, 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 **March 28, 2008**

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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:

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: ☒

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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

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- Investor Relations Release -

Rasilez®(1), the first-in-class direct renin inhibitor, reduces left ventricular hypertrophy, a powerful predictor of heart disease

- *New ALLAY study shows Rasilez alone reduced left ventricular hypertrophy (LVH) as effectively as current standard treatment(1)*
- *LVH occurs in nearly a third of high blood pressure patients(2) and doubles risk of premature cardiovascular events or death*
- *ALLAY is the latest in a series of studies to show potential of Rasilez in protecting against heart and kidney disease(3,4)*
- *Approved in more than 40 countries, Rasilez provides strong blood pressure reductions that last beyond 24 hours(5)*

Basel, March 31, 2008 Rasilez® (aliskiren), the first-in-class direct renin inhibitor, has shown clinically meaningful reductions in left ventricular hypertrophy, a proven predictor of heart disease, that are comparable to those seen with the current standard-of-care treatment(1).

Left ventricular hypertrophy (LVH), or abnormal thickening of the heart muscle, often results from high blood pressure(2). Affecting nearly a third of patients with high blood pressure, LVH decreases the heart's ability to work efficiently and more than doubles a patient's risk of premature cardiovascular events or death(6).

High blood pressure currently affects approximately one billion people worldwide and causes about 7.1 million deaths each year(7). The American Heart Association estimates that high blood pressure will cost the US economy \$66.4 billion in 2008(8).

Late-breaking results were presented today at the American College of Cardiology meeting in Chicago from the ALLAY study, part of the extensive Rasilez outcomes trial program known as ASPIRE HIGHER.

The study showed that Rasilez alone reduced LVH as effectively as the angiotensin receptor blocker (ARB) losartan (-5.4% vs -4.7% respectively) after nine months of therapy(1), despite patients having very well-controlled baseline blood pressure. With regard to the study's primary endpoint, the combination of both medicines achieved a numerically greater reduction in LVH than losartan

(1) Rasilez® is the trade name for aliskiren throughout the world, except in the US where it is known as Tekturna®

alone, but the result was not statistically significant. Alone and in combination, Rasilez was well-tolerated(1).

ALLAY is our first proof that direct renin inhibition, and aliskiren in particular, reduces thickening of heart muscle which is a key risk factor for heart disease, said Dr Scott Solomon, lead investigator of ALLAY and Director of Non-Invasive Cardiology at Brigham and Women's Hospital, Boston, USA. This is important because it provides doctors and patients with another LVH treatment alternative, while also providing effective blood pressure lowering.

The ALLAY study is the latest trial in the ASPIRE HIGHER program to highlight the organ protection potential of Rasilez, the first new kind of high blood pressure treatment in more than a decade¹. Other studies, including ALOFT, have highlighted the protective potential of Rasilez against heart and kidney diseases(3,4).

ALLAY, involving 460 overweight patients with high blood pressure and LVH from eight countries, investigated whether Rasilez reduced LVH as well as losartan, and whether a combination of the two medicines offered further LVH reductions over losartan alone¹. Patients were randomized to receive Rasilez or losartan alone, or both in combination(1).

Professor Björn Dahlöf, Associate Professor in the Department of Medicine at Sahlgrenska University Hospital/Ostra, University of Gothenburg, Sweden, said: We expect some LVH reductions simply by lowering the patient's blood pressure, but because patients in ALLAY had low baseline blood pressures, the degree of reduction with aliskiren was especially impressive.

ASPIRE HIGHER is the largest ongoing cardio-renal outcomes program and involves more than 35,000 patients in 14 trials, including three new mega-trials. ASPIRE HIGHER is studying Rasilez and direct renin inhibition in a variety of kidney and heart diseases, including diabetic kidney disease and heart failure.

Rasilez acts by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure. Rasilez is approved in more than 40 countries and is proven to provide blood pressure reductions that last beyond 24 hours(5). It was approved in the European Union in August 2007, and in the US in March 2007 under the trade name Tekturna®. Tekturna HCT®, the first single-dose combination involving Tekturna, was approved in the US in January 2008.

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 , potential , expect , or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Rasilez or regarding potential future revenues from Rasilez. 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 Rasilez to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Rasilez will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Rasilez could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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, 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 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- 1 Solomon S, Appelbaum E, Manning WJ, et al. Effect of the Direct Renin Inhibitor Aliskiren, Either Alone or in Combination With Losartan, Compared to Losartan, on Left Ventricular Mass in Patients With Hypertension and Left Ventricular Hypertrophy: The Aliskiren Left Ventricular Assessment of Hypertrophy (ALLAY) Trial. Late Breaker presentation at American College of Cardiology 57th Scientific Sessions 2008.
- 2 Left ventricular hypertrophy. MayoClinic. (Last accessed 2008 Feb 25.) Available at: <http://www.mayoclinic.com/health/left-ventricular-hypertrophy/DS00680>
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- 4 McMurray J et al. ALOFT - a 12 week safety evaluation of aliskiren 150 mg vs. placebo when added to standard therapy for stable heart failure. Oral presentation, Hotline I session at European Society of Cardiology Congress 2007.
- 5 Oh BH, Mitchell J, Herron JR, et al. Aliskiren, an oral renin inhibitor, provides dose-dependent efficacy and sustained 24-hour blood pressure control in patients with hypertension. J Am Coll Cardiol 2007;49:1157-63.
- 6 National Institutes of Health; National High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (NIH Publication No. 03-5233). Bethesda, MD: 2003. (Cited 2003 December, last accessed 2008 Feb 25.) Available at: <http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf>
- 7 Chobanian AV, Bakris GL, Black HR, et al. and the National High Blood Pressure Education Program Coordinating Committee. The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. Hypertension 2003;42:1206-1252.

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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: March 28, 2008

By: /s/ Malcolm B. Cheetham

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