NOVARTIS AG
Form 6-K
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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 June 5, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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: x Form 40-F: o

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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: o **No**: x

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- Investor Relations Release -

New data show potential of Rasilez®(1) to protect kidneys from damage independent of its proven ability to lower blood pressure

- *AVOID study shows potential kidney protection benefits of Rasilez in type 2 diabetic patients with kidney disease and high blood pressure(1)*

- *Rasilez reduced albuminuria, a key indicator of kidney disease, by an additional 20% when added to maximum dose of angiotensin-receptor blocker losartan(1),(2)*

- *First clinical trial to present data on potential kidney-protective benefits of Rasilez, independent of its proven blood pressure reductions(3)*

- *Damage to kidneys caused by diabetes is leading cause of end-stage renal disease in developed countries(1)*

Basel, June 4, 2008 Data published in this week s *New England Journal of Medicine* demonstrate that the first-in-class direct renin inhibitor Rasilez® (aliskiren), known as Tekturna® in the US, may have potential kidney-protective benefits that are independent of its already proven ability to provide powerful blood pressure reductions(1),(3). Damage to the kidneys caused by diabetes is the leading cause of end-stage renal disease in developed countries, affecting more than 1.5 million people worldwide(1),(4).

In the AVOID study, Rasilez/Tekturna reduced albuminuria by an additional 20% in type 2 diabetic patients with kidney disease who also had a diagnosis of high blood pressure. These patients were already taking the maximum dose of the angiotensin-receptor blocker (ARB) losartan, which has been shown to slow the progression of diabetic kidney disease(1),(5).

In patients with diabetes, the first sign of kidney disease is the presence of albumin in the urine, a condition called albuminuria(2). Albuminuria is a key indicator of kidney disease and cardiovascular disease(2). Reducing albuminuria is associated with a reduction of cardiovascular events(6) and slows the progression of kidney disease, which can reduce the risk of chronic kidney failure in type 2 diabetic patients with kidney disease and high blood pressure(7),(8).

These results show the potential of Rasilez to treat type 2 diabetic patients with kidney disease who are at risk of kidney failure and cardiovascular diseases, said Professor Hans-Henrik Parving, MD, of the University Hospital in Copenhagen, Denmark, the AVOID study lead investigator. The addition of Rasilez to the maximum recommended dose of losartan in patients with type 2 diabetes,

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

kidney disease and high blood pressure resulted in albuminuria reductions independent of the blood pressure lowering effects of Rasilez.

In the 24-week AVOID study involving nearly 600 patients, Rasilez/Tekturna was added to the treatment regimen of type 2 diabetic patients diagnosed with high blood pressure who were already receiving losartan and had albuminuria levels greater than 200 mg/g(1). The study showed that overall Rasilez/Tekturna (150 mg increasing to 300 mg daily) reduced albuminuria by an additional 20% when added to the maximum dose of losartan (100 mg)(1). Furthermore, a quarter of patients taking Rasilez/Tekturna added to losartan experienced albuminuria reductions greater than 50% compared to those patients taking losartan alone(1).

In addition to providing powerful blood pressure reductions that last beyond 24 hours both as monotherapy and in combination, Rasilez has now shown the potential to protect against kidney damage in type 2 diabetic patients diagnosed with high blood pressure who are extremely vulnerable to chronic kidney disease, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG.

Data from AVOID further showed that Rasilez/Tekturna added to the maximum dose of losartan had similar rates of adverse events to the placebo plus losartan group(1). Hyperkalemia (elevated potassium levels) was reported as an adverse event in 5.0% of patients taking Rasilez/Tekturna in addition to losartan, compared to 5.7% of those taking placebo plus losartan(1). Hyperkalemia as a laboratory abnormality was reported in 13.7% of patients taking Rasilez/Tekturna in addition to losartan, compared to 10.8% of the patients taking placebo plus losartan(1).

The AVOID study is one in a series of trials in the landmark ASPIRE HIGHER clinical trial program, the largest ongoing cardio-renal outcomes program, which involves more than 35,000 patients in 14 trials including three new mega-trials. The ASPIRE HIGHER program is studying the effect of direct renin inhibition in a variety of conditions, including diabetic kidney disease and heart failure(1),(9).

Rasilez/Tekturna acts by directly inhibiting renin(3), an enzyme that triggers a process leading to high blood pressure and organ damage. Rasilez/Tekturna is approved in more than 40 countries. Tekturna was approved in the US in March 2007, and in the European Union in August 2007 under the trade name Rasilez. Tekturna HCT®, the first single-dose combination involving Tekturna, was approved in the US in January 2008. Rasilez/Tekturna was discovered by Novartis and developed in collaboration with Speedel.

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 potential , may , can , risk , or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Rasilez/Tekturna or regarding potential future

revenues from Rasilez/Tekturna. 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/Tekturna to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez/Tekturna will be submitted or approved for any additional indications or labelling in any market. Nor can there be any guarantee that Rasilez/Tekturna will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Rasilez/Tekturna 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 98,000 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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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: June 5, 2008

By: /s/ MALCOLM B. CHEETHAM

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