NOVARTIS AG
Form 6-K
November 24, 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 November 21, 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:

Form 20-F: x Form 40-F: o

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: o **No: x**

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Yes: o **No: x**

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**

Novartis International AG

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- Investor Relations Release -

Rasilez HCT® receives recommendation for European approval as a single-pill combination to treat high blood pressure

- *Combination of first-in-class direct renin inhibitor Rasilez® with the diuretic HCT is twice as effective at reducing blood pressure compared to HCT alone(1)*

- *80% of patients may need multiple medicines to reach blood pressure goals; single-pill combinations offer convenience and simplify treatment regimens(2)*

- *High blood pressure affects 60% more people in Europe than North America; it is the main risk factor for stroke, which claims 650,000 lives in Europe per year(3)*

- *Positive CHMP opinion follows Swiss and US approvals of Rasilez/Tekturna HCT; European Commission decision expected in early 2009*

Basel, November 21, 2008 Rasilez HCT® (aliskiren and hydrochlorothiazide) received a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorization as a new treatment for high blood pressure. Rasilez HCT is a single-pill combination of two high blood pressure medicines first-in-class direct renin inhibitor Rasilez®(1) (aliskiren) and the diuretic hydrochlorothiazide (HCT).

Rasilez HCT is twice as effective at reducing high blood pressure compared to HCT alone(1). Rasilez, known as Tekturna® in the US, has been shown to consistently lower blood pressure beyond 24 hours(4),(5). HCT, sometimes called a water pill , is one of the most commonly used high blood pressure medicines(2).

Approximately 80% of patients require two or more medications to control their high blood pressure(2). Single-pill combinations may offer patients with high blood pressure convenience and simplify treatment regimens(2).

One in four adults worldwide suffers from high blood pressure(2). The prevalence of high blood pressure is 60% higher in Europe compared to North America and is the main risk factor for stroke, which claims 650,000 lives in Europe per year(3).

Many patients who are suffering from high blood pressure are still not achieving their treatment goals. Therefore, it is critical that we continue to offer treatments that are effective and convenient, said Professor Rainer Düsing, MD, Faculty of Medicine, University of Bonn. Studies

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

have shown that single-pill combinations may increase treatment adherence by up to 20% compared to free dose combinations of the same treatments. Rasilez HCT offers effective blood pressure lowering medications in one single pill helping patients gain better control of their high blood pressure with the convenience of having to take only one pill.

The positive CHMP opinion recommends Rasilez HCT for use in patients not controlled by either medicine alone and for patients who are adequately controlled using Rasilez and HCT as separate medicines with the same dosing regimen offered in the single-pill combination. The opinion was based on clinical trials involving more than 2,700 patients and follows recent Swissmedic approval of Rasilez HCT and US Food and Drug Administration (FDA) approval in the US where it is known as Tekturna HCT®(6),(7).

It is clear that patients with high blood pressure can benefit from more convenient treatment options that are effective and well tolerated, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. The complementary action of a direct renin inhibitor and a diuretic provides twice as much blood pressure lowering compared to the diuretic alone with the convenience of having to take only a single-pill. We are very pleased that the CHMP recognizes the beneficial value of Rasilez HCT and look forward to the European Commission decision in early 2009.

The heart and kidney protection potential of Rasilez/Tekturna, independent of its blood pressure lowering ability, is currently being investigated further in the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide involving more than 35,000 patients in 14 trials.

Rasilez/Tekturna is approved in 57 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. Rasilez HCT was approved in Switzerland in October 2008 and a European Commission decision is expected for the single-pill combination in early 2009. Tekturna HCT, the first single-pill 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 portfolio includes 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 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 recommendation, may, risk, expected, recommending, recommends, can, look forward, potential, expected, or similar expressions, or by express or implied discussions regardin potential marketing approvals for Rasilez HCT or regarding potential future revenues from Rasilez or Rasilez HCT. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Rasilez or Rasilez HCT to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez HCT will be approved for sale in any market. Nor can there be any guarantee that Rasilez or Rasilez HCT will achieve any particular levels of revenue in the future. In particular, management s

expectations regarding Rasilez or Rasilez HCT 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; 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; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, 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 97,000 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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6. Rasilez HCT Swiss Prescribing Information.
7. Tekturna HCT US Prescribing Information.

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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: November 21, 2008

By: /s/ MALCOLM B. CHEETHAM

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