NOVARTIS AG
Form 6-K
October 30, 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 October 29, 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

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: 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

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- Investor Relations Release -

Rasilez HCT®, single-pill combination of Rasilez® and diuretic, receives Swiss approval for the treatment of high blood pressure

- *Combination of first-in-class direct renin inhibitor with the diuretic HCT provides significantly greater blood pressure reductions compared to either drug alone(1),(2)*

- *Many patients are not at goal and most require two or more medicines; single-pill combinations may be more convenient and simplify treatment regimen(3)*

- *Approved in 57 countries Rasilez, known as Tekturna in the US, provides effective blood pressure reductions that last beyond 24 hours(4),(5)*

- *Swiss approval of Rasilez HCT supports expanded regulatory submissions worldwide; European Commission decision expected in early 2009*

Basel, October 29, 2008 Rasilez HCT® (aliskiren and hydrochlorothiazide), a single-pill combination of two high blood pressure medicines first-in-class direct renin inhibitor Rasilez®*(1)* (aliskiren) and the diuretic hydrochlorothiazide (HCT) has been approved by Swissmedic as a new treatment for high blood pressure.

High blood pressure is estimated to affect nearly one in four adults worldwide(3). While it is easy to measure and can be successfully managed, nearly 65% of patients with high blood pressure do not have the condition under control, underscoring the critical need for more effective treatment regimens(6). Most patients require two or more medicines to reach their target blood pressure(3). Single-pill combinations are likely to improve patient adherence and may provide a practical solution to managing high blood pressure(7).

Rasilez HCT is twice as effective at reducing blood pressure compared to HCT alone(1). The first new type of blood pressure medicine in over a decade Rasilez, known as Tekturna® in the US, provides effective blood pressure lowering that

lasts beyond 24 hours[4],[5]. HCT, sometimes called a water pill , is one of the most commonly used diuretics in the treatment of high blood pressure[3].

Up to 70% of patients may need multiple medications to help them reach blood pressure goals. Because of complex treatment regimens, patients may have a hard time adhering to their treatment plan, which can contribute to uncontrolled blood pressure, said Professor Michel Burnier, University of Lausanne, Faculty of Biology and Medicine, Head of Nephrology and Hypertension CHUV, Lausanne. By combining two therapies into a single-pill combination, Rasilez HCT

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

effectively lowers high blood pressure and provides patients with the convenience of only having to take one pill.

The Swiss approval of Rasilez HCT for patients not controlled by either medicine alone(8) follows the US approval of Tekturna HCT® earlier this year. The submission was based on clinical trials involving more than 2,700 patients(8).

Having received the US approval of Tekturna HCT earlier this year, we are pleased to now have regulatory approval of Rasilez HCT in Switzerland. This regulatory decision also supports expanded regulatory submissions in 100 countries worldwide, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. We are expecting a regulatory decision from the European health authorities for Rasilez HCT in the first quarter of 2009.

The heart and kidney protection potential of Rasilez/Tekturna, independent of its blood pressure lowering ability, is currently being further studied 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. 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 may, expected, estimated, likely, can potential, commitment, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Rasilez or 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 the Company 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 or Rasilez HCT will be submitted or approved for any additional indications or labeling 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 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; unexpected regulatory actions or delays or government regulation generally; 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 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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(3) Chobanian AV, Bakris GL, Black HR, et al. Seventh Report of the Joint National Committee on Prevention, Detection Evaluation and Treatment of High Blood Pressure. *Hypertens* 2003;42:1206-1251.

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(8) Rasilez HCT Switzerland 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: October 29, 2008

By: /s/ MALCOLM B. CHEETHAM

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