NOVARTIS AG
Form 6-K
September 10, 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 September 9, 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

Novartis International AG

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- Investor Relations Release -

RAD001 granted priority review in the US based on potential to fill unmet medical need in patients with advanced kidney cancer

- *Regulatory applications to be submitted worldwide for RAD001, proposed brand name Afinitor®; first submissions filed in the US, EU and Switzerland*

- *Data showing that RAD001 more than doubles time without tumor growth and reduced risk of disease progression by 70% now published in The Lancet*

- *RAD001 shows promise to become first once-daily oral therapy targeting mTOR to treat advanced kidney cancer*

Basel, September 9, 2008 Novartis announced today that RAD001 (everolimus) has been granted priority review by the US Food and Drug Administration (FDA). The designation is based on the drug s potential to become the first therapy to demonstrate significant benefit in patients with advanced kidney cancer after failure of standard treatment.

Novartis has also filed marketing authorization applications for RAD001 with the European Medicines Agency (EMEA) and the Swiss Agency for Therapeutic Products (Swissmedic). The proposed brand name for RAD001, Afinitor®, has been accepted by the EMEA and is currently under review in the US.

The regulatory submissions are based on data from the RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily) trial. Interim results from this study were published in *The Lancet* on July 23, 2008, and presented earlier this year at the annual meeting of the American Society of Clinical Oncology. The data show that after failure of standard treatment in patients with advanced kidney cancer, RAD001 more than doubled time without tumor growth and reduced the risk of disease progression by 70%.

Currently, patients with advanced kidney cancer who have experienced treatment failure with standard therapies have limited options, said Alessandro Riva, MD, Vice President & Global Head of Development, Novartis Oncology. The priority review designation for RAD001 brings us one step closer to offering these patients a promising new therapy.

FDA priority review status is granted to therapies that could potentially fill a currently unmet medical need and accelerates the standard review timing from ten to six months.

About RAD001

RAD001, an oral once-daily inhibitor of mTOR, is an investigational drug being studied in multiple tumor types. In cancer cells, RAD001 provides continuous inhibition of mTOR, a protein that acts as a central regulator of tumor cell division, cell metabolism and blood vessel growth. If approved, RAD001 will become the first oral, once-daily therapy that targets mTOR to treat advanced kidney cancer.

Safety findings in the RECORD-1 trial were consistent with those seen in prior Phase II studies. The most frequent adverse drug reactions in patients who took RAD001 included mouth sores (40%), feelings of tiredness/weakness (37%), and rash (25%). There was a low incidence (≥ 1% of patients listed) of grade 3 or 4 drug-related adverse events: mouth sores (3%), lung inflammation (3%), infection (3%), tiredness/feelings of weakness (4%), diarrhea (1%), mucosal inflammation (1%) and shortness of breath (1%). The trial had a low rate of adverse drug reactions leading to discontinuation among patients who took RAD001 (6%).

The safety and efficacy profile of RAD001, an investigational compound, has not yet been established in oncology and there is no guarantee that RAD001 will become commercially available. The active ingredient in RAD001 is everolimus, which is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. Certican was first approved in the EU in 2003.

In addition to renal cell carcinoma (RCC), RAD001 is being evaluated as a single agent or in combination with existing therapies in neuroendocrine tumors, lymphoma, breast, gastric, lung and other cancers, as well as tuberous sclerosis.

About renal cell carcinoma (RCC)

Kidney, or renal cell, cancer accounts for two percent of all new cancer cases worldwide with occurrence rates rising steadily around the world. In RCC, cancer cells develop in the lining of the kidney s tubes and grow into a tumor.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as priority review , potential , to be submitted , promise , proposed , promising , if approved , will , is being evaluated , or similar expressions, or by express or implied discussio regarding potential marketing approvals for RAD001 or regarding potential future revenues from RAD001. 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 RAD001 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that RAD001 will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that RAD001 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding RAD001 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; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 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 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: September 9, 2008

By: /s/ MALCOLM B. CHEETHAM

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