NOVARTIS AG
Form 6-K
September 15, 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 13, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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: x Form 40-F: o

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Yes: o **No**: x

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- Investor Relations Release -

RAD001 combined with Sandostatin® LAR® and as monotherapy controls growth of rare pancreatic neuroendocrine tumors

- *82% of patients with pancreatic neuroendocrine tumors (NET) experienced clinical benefit when treated with daily RAD001 and monthly Sandostatin LAR*

- *77% of patients with pancreatic NET experienced clinical benefit when treated with daily RAD001*

- *Data show RAD001, an oral mTOR inhibitor, has potential to become new treatment for patients with pancreatic NET who currently have limited options*

- *Phase III trials underway to confirm impact of combination RAD001 and Sandostatin LAR therapy on survival in pancreatic NET and carcinoid patients*

Basel, September 13, 2008 New data show that combination treatment with RAD001 (everolimus) and Sandostatin® LAR® (octreotide IM) and RAD001 given alone control tumor growth in patients with pancreatic neuroendocrine tumors (NET), a rare and difficult-to-treat form of cancer.

These results, from the RADIANT-1 (RAD001 In Advanced Neuroendocrine Tumors) study, were presented today at the 33rd European Society for Medical Oncology (ESMO) Congress in Stockholm, Sweden.

In the trial, patients with pancreatic NET who became resistant to chemotherapy were given either daily RAD001 combined with monthly Sandostatin LAR or daily RAD001 alone. The results showed that 82% of patients receiving combination therapy and 77% receiving monotherapy had tumors that either decreased in size or remained stable.

Pancreatic neuroendocrine tumors cause debilitating symptoms related to hormone production and typically claim the lives of patients within five years despite treatment with chemotherapy, which is the current standard of care, said James Yao, MD, Associate Professor of Medicine at The University of Texas M. D. Anderson Cancer Center. Results from this trial show the promise of RAD001, with or without Sandostatin LAR, to provide tumor shrinkage or stability and to extend time without disease progression in patients who currently have limited treatment options.

The study explores the potential of mTOR inhibition for patients with pancreatic NET by examining RAD001 alone or in combination with standard of care treatment, Sandostatin LAR. RAD001 (proposed brand name Afinitor®) is a once-daily oral therapy that continuously inhibits the mTOR protein, a central regulator of cell division and tumor blood vessel growth.

These findings begin to establish the role of RAD001 as a promising new option for patients with a rare and deadly form of cancer that historically has not responded well to any treatment, said David Epstein, President and CEO of Novartis Oncology. The combination of RAD001 and Sandostatin LAR may offer a novel treatment approach for disease and symptom control in patients with pancreatic neuroendocrine tumors who are resistant to chemotherapy.

Two Phase III trials investigating the use of RAD001 and Sandostatin LAR are underway in patients with pancreatic NET and carcinoid tumors. The endpoints will be progression-free survival and overall survival.

RADIANT-1 results

RADIANT-1 is a Phase II international, multi-center, open label, stratified study of RAD001 in 160 patients with advanced pancreatic NET, who became resistant to prior treatment with cytotoxic chemotherapy. In the monotherapy treatment group, 115 patients received RAD001 alone. In the combination treatment group, 45 patients whose tumors progressed during treatment with Sandostatin LAR continued treatment with the addition of RAD001.

The primary endpoint of RADIANT-1 was objective response rate (complete response and partial response) in the monotherapy group. The secondary endpoints included response rate in the combination treatment group, as well as response duration, safety and tolerability, progression-free survival (PFS) and overall survival, changes in plasma chromogranin A and pharmacokinetics in both groups.

Monotherapy treatment group results

Clinical benefit (overall response rate plus stable disease rate) was seen in 77% of patients. The overall response rate for patients who received RAD001 alone was 8% (CI= 3.6-14.3). All confirmed responses were partial responses; there were no complete responses. In addition, 69% of patients experienced stable disease, 14% of patients experienced progressive disease and 10% of patients had an unknown response. Responses were maintained for a median of 10.6 months (8.3-N/A). Further, the results demonstrate PFS of 9.3 months. Median overall survival had not been reached at the time of data evaluation.

The most frequent adverse events in patients taking RAD001 alone were stomatitis (44%), rash (40%), diarrhea (37%), fatigue (29%), nausea (26%), vomiting (17%), asthenia (16%), anemia (12%) and weight decrease (11%).

Combination treatment group results

Clinical benefit (overall response rate plus stable disease rate) was seen in 82% of patients. The overall response rate for patients who received RAD001 in combination with Sandostatin LAR was 4% (CI= 0.5-15.1). All confirmed responses were partial responses; there were no complete

responses. The data show that 78% of patients experienced stable disease, 2% of patients experienced progressive disease and 16% of patients had an unknown response. Further, the results demonstrate PFS of 12.9 months. Median overall survival had not been reached at the time of data evaluation.

The most frequent adverse events in patients taking RAD001 with Sandostatin LAR were stomatitis (49%), rash (40%), diarrhea (29%), fatigue (33%), nausea (33%), vomiting (13%), asthenia (11%), anemia (18%) and weight decrease (16%).

About NET

The term neuroendocrine tumor or NET, as defined by the World Health Organization, refers to a diverse mixture of tumors that include pancreatic NET and carcinoid tumors. The development of

NET is not completely understood. In some cases, NET can be part of inherited syndromes that affect the endocrine system. Since they are relatively rare among cancers, there is no routine screening. Like many other diseases, lifestyle factors, most notably smoking, may increase risk for NET.

Pancreatic NET are diagnosed in approximately five per million patient cases. Only 55% of people with pancreatic NET will survive for five years. Pancreatic NET are most commonly found in men and women between the ages of 40 and 60 years of age.

About RAD001

RAD001, an oral once daily inhibitor of mTOR, is an investigational drug being studied in multiple tumor types. The safety and efficacy profile of RAD001 has not yet been established in oncology and there is no guarantee that RAD001 will become commercially available for oncology indications. 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 European Union in 2003.

RAD001 is being studied in two large Phase III studies in advanced NETs (pancreatic NET and carcinoid). In addition to pancreatic NET, RAD001 is being evaluated as a single agent or in combination with existing therapies in renal cell carcinoma, lymphoma, breast, gastric, lung and other cancers, as well as tuberous sclerosis.

About Sandostatin LAR

Sandostatin LAR is a long-acting, injectable depot formulation of octreotide acetate, a somatostatin analogue that exerts similar pharmacologic effects on the human body as the natural hormone somatostatin. However, octreotide is even more potent than somatostatin at inhibiting growth hormone, glucagon and insulin. Based on these attributes, octreotide has been used to treat the clinical syndromes associated with NET. In addition, octreotide substantially reduces and in many cases can normalize growth hormone and/or IGF-1 levels in patients with acromegaly, a disease caused by a pituitary adenoma.

Sandostatin, the immediate release formulation of octreotide acetate for s.c injection or i.v. infusion was first approved in New Zealand in December 1987. In June 1995, the long-acting depot formulation which Novartis markets as Sandostatin LAR was approved in France. Through more than a decade and 600,000 patient years of experience, Sandostatin Injection/Sandostatin LAR has achieved a long-standing track record of sustained efficacy with a well-established safety profile.

Sandostatin LAR important safety information

Adverse reactions identified in clinical studies include nausea, abdominal pain, gas, constipation, vomiting, pain on injection, high or low blood sugar levels and slow or irregular heart rate. Many patients developed gallstones, although few patients required treatment.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential , to confirm , promise , proposed , promising , may , will , or similar expressions, or by express or implied discussions regarding potential marketing approvals for RAD001 or regarding potential future revenues from RAD001. 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 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 sale 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 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; 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; 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 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References:

(1) 508PD - A PHASE II TRIAL OF DAILY ORAL RAD001 (EVEROLIMUS) IN PATIENTS WITH METASTATIC PANCREATIC NEUROENDOCRINE TUMORS (NET) AFTER FAILURE OF CYTOTOXIC CHEMOTHERAPY. Yao, J. et al. Presented at the European Society for Medical Oncology (ESMO) 33rd Congress on 13/9/2008

(2) The Sandostatin International Site. Available at: http://www.sandostatin.com/treating_gep_ne_tumors/index.html Accessed 29/8/2008.

(3) NCCN clinical practice guidelines in oncology neuroendocrine tumors v.1.2008. Available at: http://www.nccn.org. Accessed 29/9/2008

(4) Tomassetti et al. Ann Oncol. 2005;16:1806-1810.

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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 13, 2008

By: /s/ MALCOLM B. CHEETHAM

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