

NOVARTIS AG
Form 6-K
September 17, 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 16, 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: ☒ Form 40-F: ☐

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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: ☐ **No:** ☒

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- Investor Relations Release -

Latest RAD001 study results show further increase in time without tumor growth in patients with advanced kidney cancer

- *New data, updated since ASCO, show time without tumor growth now reaches nearly 5 months with RAD001 versus 1.9 months with placebo*
- *One quarter of patients in trial remained progression-free beyond ten months of treatment*
- *RAD001 is first drug to show significant benefit after failure of initial therapy, Sutent® or Nexavar®, with potential to address unmet medical need*
- *RAD001 (proposed brand name Afinitor®) under review by regulatory authorities; potential to be first once-daily oral mTOR therapy for advanced kidney cancer*

Basel, September 16, 2008 New data continue to demonstrate the potential benefit of RAD001 (everolimus) for patients with advanced kidney cancer who have failed standard therapies.

Updated study findings from the RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily) study show that patients receiving RAD001 had no tumor growth for nearly 5 months vs. 1.9 months for patients receiving placebo (hazard ratio = 0.33 with 95% CI 0.25 to 0.43; p-value < 0.001). In addition, after more than 10 months of treatment with RAD001, 25% of patients still had no tumor growth.

The updated RECORD-1 data were presented today at the 33rd European Society for Medical Oncology (ESMO) Congress in Stockholm, Sweden.

These study results show the potential of RAD001 to continue working over an extended period of time in patients with advanced kidney cancer that progressed despite treatment with standard therapies, said Bernard Escudier, MD, Head of Immunotherapy and Innovative Therapy Unit, Gustave-Roussy Institute, Paris, France. Based on these findings, I believe RAD001 should become part of the treatment paradigm for this patient population.

RAD001 has the potential to fill a currently unmet medical need and become the first approved therapy to demonstrate significant benefit in patients with advanced kidney cancer after failure of standard treatment, including Sutent® (sunitinib) or Nexavar® (sorafenib), or both.

Earlier this year, interim results from RECORD-1 presented at the American Society of Clinical Oncology Congress were used to submit regulatory applications for RAD001 (proposed brand name Afinitor®) as a treatment for metastatic renal cell carcinoma (RCC). In the US, RAD001 was granted priority review by the US Food and Drug Administration. FDA priority review status is granted to

therapies that could potentially fill a currently unmet medical need and accelerates the standard review time from ten to six months.

We are encouraged by the continued benefit RAD001 provided to patients with advanced kidney cancer in this trial, said David Epstein, CEO and President of Novartis Oncology. Novartis is committed to bringing this new, innovative therapy to market and to exploring the potential of RAD001 beyond this specific treatment setting.

RAD001 is a once-daily oral therapy that may offer a new approach to cancer treatment by continuously inhibiting the mTOR protein, a central regulator of cell division and tumor blood vessel growth. Data suggest RAD001 has clinical activity as a single agent or in combination with other therapies in multiple types of cancer, including pancreatic neuroendocrine tumors, breast, gastric, lung and lymphoma.

RECORD-1 results

RECORD-1 is the largest Phase III clinical trial investigating the effects of an oral mTOR inhibitor in metastatic RCC. It is a randomized, double-blind, placebo-controlled multicenter trial of more than 400 patients with RCC whose cancer worsened despite prior treatment including Nexavar or Sutent, or both. In addition, prior therapy with Avastin, interferon and interleukin-2 was allowed.

The primary endpoint of RECORD-1 was progression-free survival (PFS) assessed via a blinded, independent central review and defined as the amount of time between randomization and first documented disease progression or death due to any cause. Results of the study demonstrated a statistically significant improvement in PFS for RAD001 compared to placebo (hazard ratio = 0.33 with 95% CI 0.25 to 0.43; p-value < 0.001; median PFS 4.9 months vs. 1.9 months, respectively).

Secondary endpoints included comparison of overall survival, objective response rate, quality of life and safety. There was no significant difference in overall survival between the RAD001 and placebo groups (hazard ratio = 0.82 with 95% CI 0.57 to 1.17; p-value = 0.137). The study design allowed patients to be unblinded at the time of radiological disease progression; patients receiving placebo were allowed to cross over to receive RAD001. There was no significant difference in objective response rate between the RAD001 and placebo groups (2% vs. 0% of responders). However, in a central review among patients evaluable for best percentage change in target lesions (223 and 107 in RAD001 and placebo arms, respectively), tumor shrinkage was observed in 50% of patients receiving RAD001 during the double-blind portion of the study vs. 8% of patients receiving placebo. Quality of life measurements taken throughout the study showed no significant difference between the RAD001 and placebo groups.

Safety findings in the study were consistent with those seen in prior Phase II studies. The most frequent adverse events in patients who took RAD001 included mouth sores (36%), rash (28%), feelings of weakness (23%) and tiredness (22%). There was a low incidence of grade 3 or 4 drug-related adverse events ($\geq 1\%$ of patients listed): infection (4%), mouth sores (3%), tiredness (3%), feelings of weakness (2%), lung inflammation (2%), diarrhea (2%), mucosal inflammation (1%), vomiting (1%) and difficulty breathing (2%). The trial had a low rate of adverse drug reactions leading to discontinuation among patients who took RAD001 (7%).

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.

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 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 potential, proposed, believe, should, priority review, potentially, encouraged, committed, may, suggest, or similar expressions, or by explicit 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

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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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****Sutent is a registered trademark of Pfizer Inc. Nexavar is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc.**

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 16, 2008

By: /s/ MALCOLM B. CHEETHAM

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