

NOVARTIS AG  
Form 6-K  
January 16, 2009

# 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 January 13, 2009

(Commission File No. **1-15024**)

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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:

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Form 20-F: ☒ Form 40-F: ☐

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Yes: ☐ No: ☒

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Yes: ☐ No: ☒

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 -

**New study first to confirm Sandostatin® LAR® controls tumor growth in patients with rare gastrointestinal tumors**

- *Data show significant 66% reduction in risk of disease progression versus placebo*
- *Sandostatin LAR more than doubled time without tumor growth for a median of 14 months compared to six months on placebo*
- *Results support Sandostatin LAR as first treatment after surgery in certain patients with newly diagnosed neuroendocrine tumors (NETs)*

**Basel, January 13, 2009** Sandostatin® LAR® (octreotide acetate suspension for injection) demonstrated antitumor benefit in patients with metastatic neuroendocrine tumors (NETs) of the midgut, according to interim data presented today at the 2009 Gastrointestinal Cancer Symposium of the American Society of Clinical Oncology.

After six months of treatment, patients receiving Sandostatin LAR had a 66% reduction in risk of disease progression compared to patients taking placebo ( $P=0.000072$ ). This reduction is based on findings that Sandostatin LAR halted tumor growth in 69% of patients, compared with 39% of patients receiving placebo. Patients who took Sandostatin LAR had no tumor progression for a median of 14.3 months, compared to six months for patients on placebo. This beneficial effect was seen in patients with either functioning (hormone secreting) or non-functioning (non-secreting) NETs.

The findings are from a Phase IIIb, multicenter, prospective, randomized, placebo-controlled, double-blind, study called PROMID (Placebo-controlled prospective Randomized study on the antiproliferative efficacy of Octreotide LAR in patients with metastatic neuroendocrine MIDgut tumors).

Sandostatin LAR has a proven track record of treating the severe diarrhea and flushing associated with neuroendocrine tumors and now this study demonstrates that Sandostatin LAR also helps control tumor growth in patients with metastatic neuroendocrine tumors of the midgut, said

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PROMID Lead Investigator Professor Rudolf Arnold, Philipps-University Marburg, Germany. In addition, we saw the greatest benefit in those patients who were newly diagnosed and who had fewer liver metastases (<10% hepatic tumor load), underscoring the importance of early treatment.

This is the first placebo-controlled study to confirm previous findings that suggested treatment with Sandostatin LAR could achieve stabilization of tumor growth in up to 50% of patients with NETs of various origin(1).

In recent years, a growing body of evidence has suggested that Sandostatin LAR provides antitumor effects, but these are the first data to confirm this effect from a well-designed, prospective, placebo-controlled study, said David Epstein, President & CEO of Novartis Oncology.

Studies are also underway to evaluate the benefit of combination therapy of Sandostatin LAR with our investigational mTOR inhibitor, RAD001, in patients with various types of NETs.

### **About NETs**

The term neuroendocrine tumor or NET, as defined by the World Health Organization, refers to a diverse mixture of tumors originating from the interface between the endocrine (hormonal) system and the nervous system, and includes carcinoid tumors and pancreatic NETs. Treatment options for patients with NETs are limited, with surgery being the only chance for cure. When the tumor is inoperable, the objectives of treatment are to control the potentially life-threatening symptoms (syndromes) caused by hormone secretion and to extend patient survival by reducing tumor volume or by stopping the tumor from growing. The PROMID study included only patients with well-differentiated metastatic midgut tumors.

### **About PROMID**

PROMID is a Phase IIIb study conducted at 18 sites in Germany to evaluate the antitumor effect of Sandostatin LAR in patients with NETs. The study included 85 patients who were treated with either Sandostatin LAR or placebo until tumor progression. All patients in the study were treatment-naïve, had locally inoperable or metastatic NETs with the primary tumor within the midgut, were without curative therapeutic options and had tumors that were functionally active (i.e. tumors that secrete various hormones and bioactive amines, causing symptoms such as diarrhea or flushing) or inactive. The study was sponsored by Novartis.

The safety findings observed in the PROMID study were consistent with those seen in previous studies of Sandostatin LAR in patients with NETs. The most frequently observed serious adverse events affected the gastrointestinal tract (octreotide LAR arm: n=6, placebo arm n=8), the hematopoietic system (octreotide LAR arm: n=5, placebo arm n=1) and the general health status (fatigue, fever; octreotide LAR arm: n=7, placebo arm n=2). Serious adverse events occurred in 11 Sandostatin LAR treated patients and 10 placebo recipients. Discontinuation of treatment because of adverse effects occurred in two of 42 patients in the octreotide LAR and in zero of 43 patients in the placebo arm.

### **About Sandostatin LAR**

Sandostatin LAR is a long-acting, injectable depot dosage formulation of octreotide acetate, a somatostatin analog 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 subcutaneous injection or intravenous 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**

Among the very common ( $\geq 1/10$ ) adverse drug reactions observed in clinical studies with Sandostatin LAR are diarrhea, abdominal pain, nausea, constipation, flatulence, headache, cholelithiasis, hyperglycaemia and injection-site localized pain.

Common ( $\geq 1/100$ ,  $< 1/10$ ) adverse drug reactions include dyspepsia, vomiting, abdominal bloating, steatorrhoea, loose stools, discoloration of feces, dizziness, hypothyroidism, thyroid dysfunction (e.g., decreased thyroid stimulating hormone [TSH], decreased Total T4 and decreased Free T4), cholecystitis, biliary sludge, hyperbilirubinaemia, hypoglycaemia, impairment of glucose tolerance, anorexia, elevated transaminase levels, pruritus, rash, alopecia, dyspnoea and bradycardia.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, suggested, could, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Sandostatin LAR, potential future approvals for RAD001, or regarding potential future revenues from Sandostatin LAR or RAD001. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Sandostatin LAR will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that RAD001 will be approved for sale for any oncology indication in any market. Neither can there be any guarantee that Sandostatin LAR or RAD001 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Sandostatin LAR and 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 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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### **References**

(1) Arnold et al Clin Gastro Hepatol 2005; Saltz et al. Cancer 1993; Arnold et al. Gut 1996; Di Bartolomeo et al Cancer 1996

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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: January 13, 2009

By: /s/ MALCOLM B. CHEETHAM

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