

NOVARTIS AG
Form 6-K
May 19, 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 May 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:

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Form 20-F: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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: ☐ **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 -

Strength and innovation of Novartis Oncology products and pipeline with potential to improve patient treatment demonstrated by more than 170 abstracts at ASCO annual meeting

Unprecedented amount of research reflects depth and breadth of collaboration with investigators worldwide to develop new treatments for diverse forms of cancer

Plenary session to highlight impact of Zometa[®], the leading IV bisphosphonate, on relapse rate of patients with early-stage breast cancer

Four oral sessions to feature RAD001, first oral once-daily continuous inhibitor of mTOR, including first results of RECORD-1 study in renal cell carcinoma

Updated Phase II results with Tasigna[®] in Philadelphia chromosome-positive chronic myeloid leukemia to be presented

Basel, May 15, 2008 Novartis Oncology announced today that the 44th annual meeting of the American Society of Clinical Oncology (ASCO) will include an unprecedented amount of research drawing from Novartis Oncology's robust pipeline of investigational compounds and existing cancer therapies. Novartis Oncology's cancer therapies will be the subject of more than 170 abstracts at the meeting, and will be highlighted in a plenary session, as well as seven oral presentations.

A plenary session will feature the first efficacy results from the ABCSG-12 study, looking at the impact of Zometa[®] (zoledronic acid) on disease-free survival in patients with early-stage breast cancer (*Abstract #LBA4: Sunday, June 1, 2008; 1:45 PM to 2:00 PM CDT*). In addition, late-breaking data on the role of RAD001 (everolimus) as a potential new treatment option for patients with advanced kidney cancer who have failed standard therapies will be presented in an oral session (*Abstract #LBA5026: Saturday, May 31, 2008; 4:30 PM-4:45 PM CDT*).

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This is a particularly exciting year for Novartis Oncology in advancing research and touching the lives of thousands of cancer patients, said David Epstein, CEO & President of Novartis Oncology. Our scientific presence at ASCO shows that Novartis is a leader in delivering potential new cancer treatments and in demonstrating productive collaboration with key investigators across the intricate spectrum of cancer research.

Six Novartis oncology compounds are currently in late-stage development with the potential for registration over the next five years. These compounds include RAD001 (renal cell carcinoma and other cancers), ASA404 (non-small cell lung cancer), SOM230 (Cushing's disease, refractory carcinoid tumors and acromegaly), LBH589 (cutaneous T-cell lymphoma and other cancers),

EPO906 (ovarian cancer), and PKC412 (acute myelogenous leukemia and aggressive systemic mastocytosis).

Other highlights of data to be presented include:

The first results from the CALGB trial 79809, of the effects of Zometa on bone mineral density in premenopausal women who develop ovarian failure due to adjuvant chemotherapy (*Abstract #512: Saturday, May 31, 2008; 5:00 PM-5:15 PM CDT*).

Results from a Phase II study of bevacizumab and RAD001 in the treatment of advanced renal cell carcinoma (RCC) (*Abstract #5010: Saturday, May 31, 2008; 2:00-PM-2:15 PM CDT*).

Data from a multicenter Phase I clinical trial of daily and weekly RAD001 in combination with weekly paclitaxel and trastuzumab in patients with Her2-overexpressing metastatic breast cancer with prior resistance to trastuzumab (*Abstract #1003: Monday, June 2, 2008; 4:30 PM-4:45 PM CDT*).

Analysis of results from a Phase II study of RAD001 in patients with recurrent endometrial carcinoma (*Abstract #5002: Sunday, June 1, 2008; 5:30 PM-5:45 PM CDT*).

Updated Phase II results on Tasigna in patients with imatinib-resistant chronic myeloid leukemia in chronic phase (*Abstract #7010: Monday, June 2; 10:30 AM 10:45 AM CDT*).

Phase II data comparing safety and efficacy between squamous and non-squamous non-small cell lung cancer patients receiving ASA404 (*Abstract #8072: Sunday, June 1, 2008; 2:00 PM-6:00 PM CDT*).

Novartis Oncology Products and Compounds

Zometa is currently used for the prevention of skeletal-related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with advanced malignancies involving bone.

RAD001 (everolimus) is an investigational oral once-daily inhibitor of mTOR, a protein that controls tumor cell division and blood vessel growth. Everolimus is approved 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 and is available in more than 60 countries.

Tasigna® (nilotinib) is a next-generation tyrosine kinase inhibitor recently approved in the US and EU as second-line therapy for patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML).

ASA404 is an investigational small-molecule Tumor-VDA that selectively disrupts existing tumor blood vessels.

Zometa Safety Information

In clinical studies, the safety profile with Zometa was similar to that of pamidronate. Zometa has been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics, and other potentially nephrotoxic drugs. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of diluent.

In clinical trials in patients with bone metastases and hypercalcemia of malignancy (HCM), Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea, and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy, and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available as to whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures.

Please see full Prescribing Information.

Tasigna Safety Information

Because taking Tasigna with food may increase the amount of drug in the blood, Tasigna should not be taken with food and patients should wait at least two hours after a meal before taking Tasigna. In addition, no food should be consumed for at least one hour after the dose is taken.

In countries where it is approved, Tasigna is indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia in adult patients resistant or intolerant to at least one prior therapy including Glivec. The effectiveness of Tasigna is based on confirmed hematologic and unconfirmed cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

The most frequent Grade 3 or 4 adverse events for Tasigna were primarily hematological in nature and included neutropenia and thrombocytopenia. Elevations were seen in bilirubin, liver function tests, lipase enzymes and blood sugar, which were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation. Pancreatitis was reported in less than 1% of cases. The most frequent non-hematologic drug-related adverse events were rash, pruritus, nausea, fatigue, headache, constipation, and diarrhea. Most of these adverse events were mild to moderate in severity.

Tasigna should be used with caution in patients with uncontrolled or significant cardiac disease (e.g., recent heart attack, congestive heart failure, unstable angina or clinically significant bradycardia), as well as in patients who have or may develop prolongation of QTc. These include patients with abnormally low potassium or magnesium levels, patients with congenital long QT syndrome, patients taking anti-arrhythmic medicines or other drugs that may lead to QT prolongation. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Close monitoring for an effect on the QTc interval is advisable and a baseline ECG is recommended prior to initiating therapy with Tasigna and as clinically indicated.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as pipeline, to develop, to highlight, to feature, to be, will, potential, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications or labelling for existing products, or regarding potential future revenues from such products. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications or labelling will be approved for any

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existing products. Nor can there be any guarantee that any such products will achieve any particular levels of revenue in the future. In particular, management's expectations 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, 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 growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and 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: May 16, 2008

By: /s/ MALCOLM B. CHEETHAM

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