NOVARTIS AG
Form 6-K
December 05, 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 December 4, 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
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

More than 200 abstracts at ASH and SABCS reveal potential compelling patient benefits from Novartis Oncology current and pipeline therapies

- *Tasigna front-line data demonstrating potential in newly diagnosed patients with a life-threatening type of leukemia to be featured in two oral sessions at ASH*

- *Exjade results at ASH to show benefits for chronically transfused patients by significantly reducing toxic iron that can damage key organs*

- *New long-term data from major independent breast cancer trial at SABCS to report on optimal post-surgery treatment strategy, Femara vs. tamoxifen*

- *Multiple Zometa studies at SABCS to affirm anti-cancer activity in patients with early-stage breast cancer*

Basel, December 4, 2008 More than 200 abstracts from therapies across the Novartis Oncology portfolio will be presented at two December medical congresses, providing new data and profiling potential patient benefits from ongoing collaboration with the oncology community.

The American Society of Hematology (ASH) annual meeting, beginning December 6th in San Francisco, CA, will feature 34 oral presentations on the Novartis Oncology portfolio including 20 on Glivec® (imatinib), six on Tasigna® (nilotinib), five on Exjade® (deferasirox) and three on products in development. The CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), beginning December 10th, will feature four oral presentations, including three on Femara® (letrozole) and one on Zometa® (zoledronic acid).

Our robust portfolio and dedication to oncology research is ultimately about providing patients and their physicians with new treatment options to address unmet medical needs, said David Epstein, CEO and President of Novartis Oncology. We are pleased that our ongoing work with experts in the fields of oncology and hematology continue to provide valuable new insights across multiple cancer types.

The most significant presentations at ASH include:

- **Tasigna** data showing its benefit in the first-line treatment setting for patients with chronic myeloid leukemia, in two oral presentations *(ASH Abstracts #181 & 446; Monday, December 8, 2008; 7:00 AM PST & 1:45 PM PST, respectively)*

- Cardiac data from the landmark EPIC trial, demonstrating significant benefit with **Exjade** in patients with transfusion-dependent anemias *(ASH Abstract #3873; Monday, December 8, 2008;*

5:30 PM PST). More than 10 additional abstracts from the EPIC trial in patients with different underlying anemias will also be presented

- **RAD001** data demonstrating benefit in patients with relapsed and/or refractory Waldenström Macroglobulinemia *(ASH Abstract #1011; Saturday, December 6, 2008; 5:30 - 7:30 PM PST)*

- More than 10 abstracts on **panobinostat (LBH589**), showing early activity across a broad range of cancers, including acute myeloid leukemia, cutaneous t-cell lymphoma, multiple myeloma and mantle cell lymphoma

The most significant presentations at the CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) will include:

- New data, presented in an oral session, from major international BIG 1-98 trial evaluating Femara vs. tamoxifen and the sequencing of the two therapies show evidence of optimal treatment strategy for postmenopausal women with breast cancer *(SABCS Abstract #13; Thursday, December 11, 2008; 9:45 - 10:00 AM CST)*

- The addition of zoledronic acid to neoadjuvant chemotherapy may influence pathological response exploratory evidence for direct anti-tumor activity in breast cancer (AZURE subgroup analysis) *(SABCS Abstract #5101; Saturday, December 13, 2008; 5:00 - 7:00 PM CST).* A total of nine **Zometa** abstracts, of which six will show the potential anti-cancer benefits of the therapy

- The latest **RAD001 data**, including six abstracts, and supporting the need for additional studies to determine its potential role in the treatment of breast cancer

Other highlights of data to be presented at ASH include:

Glivec

- A Phase III, Randomized, Open-Label Study of 400 Mg Versus 800 Mg of Imatinib Mesylate in Patients with Newly Diagnosed, Previously Untreated Chronic Myeloid Leukemia in Chronic Phase (CML-CP) Using Molecular Endpoints: 1-Year Results of TOPS (Tyrosine Kinase Inhibitor Optimization and Selectivity) Study (ASH Abstract #335: Monday, December 8, 2008; 12:00 PM PST)

- International Randomized Study of Interferon Versus STI571 (IRIS) 7-Year Follow-up: Sustained Survival, Low Rate of Transformation and Increased Rate of Major Molecular Response in Patients with Newly Diagnosed CML-CP Treated with Imatinib (ASH Abstract #186: Monday, December 8, 2008; 8:15 AM PST)

Exjade

- Efficacy and Safety of Deferasirox (Exjade®) in Patients with Transfusion-Dependent Anemias: 1-Year Results from the Large, Prospective, Multicenter EPIC Study. (ASH Abstract #3875; Monday, December 8, 2008; 5:00 PM PST)

- Efficacy and Safety of Deferasirox (Exjade®) during 1 Year of Treatment in Transfusion-Dependent Patients with Myelodysplastic Syndromes: Results from EPIC Trial (ASH Abstract #633 - Monday, December 8, 2008; 3:30 PM PST)

LBH589 (panobinostat)

- Phase II trial of Oral Panobinostat (LBH589) in Patients with Refractory Cutaneous T-Cell Lymphoma (ASH Abstract #1005 Saturday, December 6, 2008; 5:30 PM PST)

- Phase IA/II Study of Oral Panobinostat (LBH589), a Novel Pan-Deacetylase Inhibitor (DACi) Demonstrating Efficacy in Patients with Advanced Hematologic Malignancies (ASH Abstract #958 Saturday, December 6, 2008; 5:30 PM PST)

- A Phase II Study of Oral Panobinostat (LBH589) in Adult Patients with Advanced Refractory Multiple Myeloma (ASH Abstract #2774 Sunday, December 7, 2008; 6:00 PM PST)

Other highlights of data to be presented at SABCS include:

RAD001

- Multicenter Phase I clinical trial of daily and weekly RAD001 (everolimus) in combination with vinorelbine and trastuzumab in HER-2-overexpressing metastatic breast cancer with prior resistance to trastuzumab (SABCS Abstract #406: Friday, December 12, 2008; 7:00 - 9:00 AM CST)

- RAD001 (everolimus) in combination with weekly paclitaxel and trastuzumab in patients with HER-2-overexpressing metastatic breast cancer with prior resistance to trastuzumab: a multicenter Phase I clinical trial (SABCS Abstract #3119: Friday, December 12, 2008; 5:00 - 7:00 PM CST)

About Glivec

Glivec is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ CML. Glivec is also approved in the EU, US and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GIST), which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In Japan, Glivec is approved for the treatment of patients with Kit (CD117)-positive GIST. In the EU, Glivec is also approved for the treatment of adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL. Glivec is also approved for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. Glivec is also approved for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). Glivec is also approved for hypereosinophilic syndrome and/or chronic eosinophilic leukemia (HES/CEL).

The effectiveness of Glivec is based on overall hematological and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on hematological response rates in SM, HES/CEL, on objective response rates and progression-free survival in unresectable and/or metastatic GIST, on recurrence free survival in adjuvant GIST, and on objective response rates in DFSP. Increased survival in controlled trials has been demonstrated only in newly diagnosed chronic phase CML and GIST.

Not all indications are available in every country.

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, abdominal pain, myalgia, arthralgia, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, dermatitis, eczema, fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well-tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy, with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubinemia observed when Glivec was combined with high dose chemotherapy.

Rare/serious adverse reactions include: sepsis, pneumonia, depression, convulsions, cardiac failure, thrombosis/embolism, ileus, pancreatitis, hepatic failure, exfoliative dermatitis, angioedema, Stevens-Johnson syndrome, renal failure, fluid retention, edema (including brain, eye, pericardium, abdomen and lung), hemorrhage (including brain, eye, kidney and gastrointestinal tract),

diverticulitis, gastrointestinal perforation, tumor hemorrhage/ necrosis, hip osteonecrosis/avascular necrosis.

Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Cardiac screening should be considered in patients with HES/CEL, and patients with MDS/MPD with high level of eosinophils (echocardiogram, serum troponin level).

Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

About Tasigna

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.

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.

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.

About Exjade

Exjade is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). It is approved in 90 countries including the US, Switzerland, Japan and the countries comprising the European Union. The approved indication may vary depending upon the individual country.

Exjade is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.

There have been post-marketing reports of acute renal failure, hepatic failure and cytopenias in patients treated with Exjade. Monthly monitoring of serum creatinine, proteinuria, serum

transaminases and blood counts is recommended, and the dose of Exjade should be modified or interrupted if necessary. More frequent creatinine monitoring is recommended in patients with an increased risk of renal complications. Upper gastrointestinal ulceration and hemorrhage have been reported and caution should be exercised when combined with drugs with ulcerogenic potential. Skin rashes, including hypersensitivity reactions, have been reported. Exjade should be interrupted if severe rash develops and discontinued if severe hypersensitivity reaction occurs. Auditory and ophthalmic testing should be conducted annually.

Exjade should not be taken with aluminium-containing antacids. Caution should be exercised when Exjade is combined with drugs metabolized through CYP3A4.

The most common adverse reactions are nausea, vomiting, diarrhea, abdominal pain, rash, non-progressive increase in serum creatinine, increased transaminases, abdominal distension, constipation, dyspepsia, proteinuria and headache.

Please visit www.exjade.com for more information.

About Femara

Femara is a leading once-daily oral aromatase inhibitor available in more than 100 countries, including the US, major European countries and Japan. It is approved for a number of indications:

- Adjuvant treatment of postmenopausal women with hormone-receptor-positive early breast cancer

- Extended adjuvant treatment of hormone-dependent early breast cancer in postmenopausal women who have had prior standard adjuvant tamoxifen therapy for five years

- First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer

- Advanced breast cancer in women with natural or artificially induced postmenopausal status after relapse or disease progression who have been treated with antiestrogens

- Pre-operative therapy in postmenopausal women with localized hormone receptor-positive breast cancer which allows subsequent breast-conserving surgery in patients not originally considered suitable for this type of surgery

Not all indications are available in every country. Subsequent treatment after surgery should be in accordance with the standard of care.

Femara should not be taken by women who have previously had any unusual or allergic reactions to letrozole or any of its ingredients. Femara should not be taken by women who are pregnant or breastfeeding. Only women who are of postmenopausal endocrine status should take Femara. Patients with severe liver impairment should be monitored closely. The use of Femara in patients with significantly impaired kidney function warrants careful consideration.

The most common side effects of Femara are hot flushes, fatigue, joint pain and nausea. Other common side effects are anorexia, appetite increase, peripheral edema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, hair loss, increased sweating, rash, muscle pain, bone pain, arthritis, osteoporosis, bone fractures, weight increase, hypercholesterolemia and depression. Other rare, but potentially serious adverse events include leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis and ischemic cardiovascular disease.

About Zometa

Zometa is indicated for the treatment of 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. Zometa is approved and indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a convenient 4 mg, 15-minute infusion.

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 dilutent.

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 to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures.

Please see full Prescribing Information.

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.

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.

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

About LBH589 (panobinostat)

Panobinostat (LBH589), is an investigational pan-deacetylase (DAC) inhibitor which interferes with many of the pathophysiological mechanisms involved in cancer. Specifically, panobinostat causes an increased acetylation of both histone and non-histone proteins which are implicated in

oncogenesis and thereby modulates their activity. In this way, panobinostat selectively induces the death of tumor cells. To date, objective clinical responses in patients with hematologic and solid malignancies have been observed with panobinostat.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, pipeline, to be, to show, ca to report, to affirm, will, may, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products. 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 any new products will be approved for sale in any market, or that any new indications will be approved for existing products in any market, or that such products will achieve any particular revenue levels. 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; 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.

# # #

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Geoffrey Cook
Novartis Oncology Communications
+1 862 778 2675 (direct)
+1 973 652 7927(mobile)
geoffrey.cook@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

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: December 4, 2008

By: /s/ MALCOLM B. CHEETHAM

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