

NOVARTIS AG
Form 6-K
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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 9, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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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Yes: **No:**

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- Investor Relations Release -

Novartis set to sustain its leading global position in oncology with portfolio targeting various tumors and life-threatening diseases

- *Plans to expand oncology portfolio: Exploring new indications for marketed drugs, robust development pipeline progressing with 16 new molecular entities*
- *Two US/EU oncology submissions on track for end-2009: Tasigna for first-line use in a form of CML and Zometa in adjuvant breast cancer patients*
- *Up to five regulatory submissions planned for 2010 based on results from ongoing clinical trials involving Afinitor, SOM230, LBH589 and EPO906*
- *Targeted therapies now represent majority of Novartis oncology pipeline, investments drive progress in early portfolio with focus on biomarkers*
- *Rapid progress in other areas of highly competitive Pharmaceuticals pipeline:*
- *FTY720 (MS) on track for US/EU submissions by end-2009 based on clinical data with more than 5,300 patient-years of experience*
- *EU submission accelerated to end-2009 for additional use of Lucentis in diabetic macular edema, a diabetes-related cause of blindness*

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Basel, December 9, 2009 Novartis is set to sustain its leading global position in oncology by expanding the range of indications for several marketed therapies and developing its competitive development pipeline with 16 new molecular entities focused on various life-threatening diseases, senior executives told investors at a meeting today.

Plans include regulatory submissions by the end of 2009 to expand the use of the marketed products *Tasigna* and *Zometa* for treatment of various cancers. Up to five other regulatory submissions are possible in 2010 involving *Afinitor* and other development compounds based on the outcome of ongoing clinical trials in various tumor types.

Novartis has been leading the pharmaceuticals industry in delivering growth in 2009 from recently launched products, according to IMS Health. Contributions from products launched in the last two years rose to 18% of net sales in the 2009 third quarter from 8% in the 2008 first quarter. Oncology will play a key role in this transformation ahead of the end of market exclusivity for *Diovan* (hypertension) in Europe (2011) and the US (2012).

We have a productive and innovative pipeline that holds promise for many patients, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. The benefits of our sustained R&D investments are reflected in the nearly 30 major regulatory approvals achieved so far in 2009 in

the US, Europe, Japan and China. A further 27 projects are currently in late-stage clinical trials, while eight more projects are awaiting regulatory decisions.

Novartis expanding one of the industry's top oncology portfolios

The Novartis oncology research strategy focuses on identifying alterations in critical cancer genes and developing medicines targeted directly at components of these molecular pathways. This strategy has enabled Novartis to bring five novel oncology compounds to market since 2001 and is driving the development of new therapies that have the potential to significantly benefit patients. Highlighting the success of this strategy, the majority of oncology pipeline compounds are targeted therapies.

Over the last several years we have dramatically grown our presence in oncology to become the second largest company based on our ability to bring novel medicines to market that provide substantial benefit to patients, said David Epstein, President and CEO, Novartis Oncology and Novartis Molecular Diagnostics. We are poised to continue to help cancer patients by addressing key unmet needs and to deliver sustained value through both our strong portfolio of marketed products and robust pipeline.

The Novartis oncology pipeline includes 16 compounds in research and development across diverse target tumor types and molecular pathways of cancers where there is significant unmet medical need. Six innovative new molecular entities are currently in pivotal trials, while nine additional NMEs are in the exploratory phase. Many programs are also exploring new indications for the marketed medicines *Afinitor* and *Tasigna*.

Two major oncology regulatory submissions are planned by the end of 2009:

- *Zometa* (zoledronic acid) is planned to be submitted for US and EU approval for adjuvant use in certain types of patients with breast cancer based on results from the Austrian Breast & Colorectal Cancer Study Group (ABCSCG) 12 study, the first large Phase III trial to substantiate its anticancer effect.
- *Tasigna* (nilotinib) is planned to be submitted for US and EU approval for first-line use in patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) based on positive results of the ENESTnd study that showed significant efficacy improvement over *Gleevec/Glivec* (imatinib).

Based on the outcome of ongoing clinical trials, up to five additional regulatory submissions are planned for 2010 for *Afinitor* (for two indications) and three new molecular entities in clinical development trials: SOM230 (pasireotide) in Cushing's disease, LBH589 (panobinostat) in Hodgkin's lymphoma and EPO906 (patupilone) in ovarian cancer. Also presented at the event was a review of the recently in-licensed Janus kinase (JAK) inhibitor in hematologic diseases.

Among the portfolio of oncology projects:

- **Tasigna** (nilotinib) is a potent and selective inhibitor of the Bcr-Abl protein, which causes production of cancer cells in Ph+ CML. New data from a large Phase III trial presented recently at the American Society of Hematology (ASH) meeting showed *Tasigna* produced faster and deeper responses compared to *Gleevec/Glivec* as a first-line treatment in Ph+ CML. These results showed statistically significant improvement with *Tasigna* over *Glivec* in every efficacy measure designated, including prevention of progression to accelerated or blastic phase. US and EU regulatory submissions in first-line use for Ph+ CML are planned in December 2009. Clinical trials are also underway examining the use of *Tasigna* in CML patients with suboptimal response to *Glivec*, as well as Phase III clinical trials investigating the effectiveness of *Tasigna* in treating patients with gastrointestinal stromal tumors (GIST) as first-line and additional lines of therapy. A Phase III study in patients with cKit-mutant

melanoma is planned to start in 2010. Studies in patients with pulmonary arterial hypertension are also ongoing.

- **SOM230** (pasireotide) is in development for treatment of Cushing's disease, carcinoid tumors and acromegaly. SOM230 is a somatostatin analog with broad binding affinity to multiple somatostatin receptor subtypes. Based on results from a pivotal trial in Cushing's disease, regulatory submission is planned for 2010. A Phase III trial for acromegaly recently reached its patient accrual target, while a Phase III trial in patients with carcinoid tumors is also ongoing.
- **Afinitor** (everolimus) was recently approved in Switzerland and launched in the US and EU in 2009 for the treatment of advanced renal cell carcinoma. In addition, results from the Phase II RADIANT-1 study presented earlier this year at the 11th World Congress on Gastrointestinal Cancer showed that 84% of patients with advanced pancreatic neuroendocrine tumors (pNET) treated with *Afinitor* and *Sandostatin LAR* experienced a decrease in tumor size and/or no tumor growth. The RADIANT-2 study, a Phase III trial of *Afinitor* in other NET types, is ongoing. RADIANT-3, a Phase III trial to further investigate *Afinitor* as a potential treatment option for patients with pNET, is also ongoing. Initial results from both trials are expected in mid-2010, with potential regulatory submissions planned by the end of 2010. A US submission is also set for 2010 in tuberous sclerosis complex (TSC).
- **ASA404** (vadimezan) is a potentially first-in-class tumor-vascular disrupting agent being developed for non-small cell lung cancer (NSCLC). Two Phase III trials are evaluating ASA404 in combination with standard chemotherapy as a treatment for locally advanced or metastatic NSCLC of squamous or non-squamous histology. The ATTRACT-1 Phase III trial investigating ASA404 as first-line therapy completed enrollment in the third quarter of 2009. The ATTRACT-2 Phase III trial investigating ASA404 as second-line therapy is currently enrolling patients. Pending trial outcomes, regulatory submission for use in NSCLC is expected in 2011. ASA404 is also being investigated in combination with taxanes as a first-line treatment of HER2-negative metastatic breast cancer. A Phase IB/II clinical trial is set to start in 2010.
- **LBH589** (panobinostat) is a highly potent pan-histone deacetylase inhibitor targeting multiple oncogenic pathways, with development focused on hematological disease. In Hodgkins lymphoma, a pivotal Phase II third-line trial has completed enrollment with regulatory submissions planned in 2010. A Phase III trial in Hodgkin lymphoma is planned to start in 2010, while a Phase III trial in relapsed multiple myeloma patients is planned to begin by the end of 2009.
- **TKI258** is an inhibitor of VEGFR1-3, FGFR 1-3 and PDGFR that results in potent anti-angiogenic activity. A Phase III trial in metastatic renal cell carcinoma (mRCC) patients who are failing VEGF and mTOR inhibitor therapies is planned to start in the second half of 2010. Initial data in this indication showed that TKI258 therapy was associated with 6.1 months of progression-free survival (median) in heavily pre-treated mRCC patients, which is considered to compare well to current treatments. TKI258 has the potential to be combined with everolimus in kidney cancer, and it is also being studied in breast and bladder cancer as well as multiple myeloma.
- **INCB018424** is an oral, selective Janus kinase (JAK) inhibitor with high potential in hematologic diseases characterized by over-production of blood cells caused by mutations in the JAK pathway. The compound was recently in-licensed from Incyte Corporation. Clinical studies have shown that INCB018424 reduces splenomegaly in patients with myelofibrosis, a key efficacy parameter in myeloproliferative neoplasms. INCB018424 is currently being studied in two ongoing Phase III trials in myelofibrosis. Development is also ongoing in polycythemia vera. The first regulatory submission for myelofibrosis is planned for 2011.

Non-Oncology pipeline making rapid progress to address unmet needs

Progress among non-Oncology development projects highlighted at the event included the accelerated EU submission of *Lucentis* (diabetic macular edema) a year ahead of schedule as well as the EU submission of TOBI-TIP (cystic fibrosis) and the US/EU submissions for *Zalbin/Joulferon* (chronic hepatitis C). FTY720 (multiple sclerosis) is also on track for planned US/EU submissions by the end of 2009.

Novartis has a full pipeline of 148 projects in overall clinical development, including more than 60 NMEs. Using pathway-based research and biomarkers, along with a greater focus on patient outcomes, Novartis is increasing its R&D emphasis on specialty disease areas and the potential of targeted therapies.

Development projects highlighted include:

- **ABF656** (albinterferon alfa-2b), a treatment for chronic hepatitis C, was submitted in November for regulatory approval in the US as *Zalbin* and is on track to be filed by the end of 2009 in the EU as *Joulferon*. In Phase III studies, ABF656 (dosing every two weeks) showed similar efficacy to peginterferon alfa-2a (weekly dosing), a current standard of care, but required half the number of injections. ABF656 is being developed and will be marketed in partnership with Human Genome Sciences.
- **AFQ056** has the potential to become the first approved treatment for Parkinson's disease levodopa-induced dyskinesia (PD-LID). Affecting 40% of patients with Parkinson's disease, levodopa-induced dyskinesia is a side effect that can occur with prolonged use of levodopa and is marked by abnormal, involuntary movements. AFQ056 showed positive results in a proof-of-concept trial in PD-LID, and enrollment has now started for a Phase IIb trial.
- **ACZ885** (canakinumab) is a fully human monoclonal antibody that blocks action of the inflammatory protein interleukin-1 beta. Already approved in the US, Europe and some other markets under the brand name *Ilaris* for treatment of cryopyrin-associated periodic syndrome (CAPS), a rare life-long auto-inflammatory disease, clinical trials are ongoing in other diseases in which IL-1 beta is believed to play an important role. Other diseases include gout, chronic obstructive pulmonary disease (COPD), type 2 diabetes and systemic juvenile idiopathic arthritis (SJIA). A Phase III trial was recently started after recent Phase II data showed ACZ885 provided patients suffering from difficult to-treat gout with superior pain relief and reduced the risk of recurrent flares by 94% versus an injectable corticosteroid. Gout is one of the most painful forms of arthritis with acute flares and chronic inflammation that can damage joints and bone.
- **AIN457** targets interleukin-17 alpha, a major trigger of inflammation in a variety of serious diseases including uveitis, psoriasis and rheumatoid arthritis. Based on proof-of-concept studies showing that AIN457 delivered a rapid response, Phase III trials were started in November for the use of AIN457 in treating a certain type of uveitis, with a possible EU regulatory submission in 2010. Phase II trials have also been started for psoriasis and rheumatoid arthritis.
- **BAF312**, a sphingosine 1-phosphate (S-1-P) receptor modulator, has the potential to follow FTY720 (fingolimod) as a next-generation oral treatment for relapsing forms of multiple sclerosis. A Phase II study was started in March with the aim to determine the dose-response curve for MRI-based efficacy of BAF312 compared with placebo in patients with relapsing-remitting multiple sclerosis (RRMS) and to characterize its safety and tolerability for dose selection in Phase III studies. Results from this Phase II study are expected in 2010.

- **FTY720** (fingolimod), a once-daily oral compound in development for certain forms of multiple sclerosis, is on track for completion of regulatory submissions by the end of 2009 in Europe

and the US, where it has been granted fast-track status that enabled a rolling submission process initiated in June. FTY720 has a well-studied safety profile with more than 5,300 patient-years of exposure, including patients now in their sixth year of treatment. FTY720 was licensed from Mitsubishi Tanabe in Japan.

- **Lucentis** (ranibizumab), the leading approved therapy for the wet form of age-related macular degeneration (wet AMD), is planned to be submitted in Europe in December for visual impairment due to diabetic macular edema (DME), an eye condition related to long-standing diabetes that may lead to blindness. New data in other treatment areas continue to demonstrate the potential of *Lucentis*. Two Phase III studies BRAVO and CRUISE conducted by Genentech showed early and sustained improvement in vision in patients with retinal vein occlusion (RVO). Another study, EVEREST, showed the combination of *Visudyne* and *Lucentis* improved eyesight and significantly reduced vessel abnormalities in patients with polypoidal choroidal vasculopathy, a subtype of wet AMD that involves the growth of tiny, abnormal blood vessels under the retina. Genentech holds the US rights for *Lucentis*.

- **QAB149** (indacaterol), a once-daily bronchodilator for adult patients with chronic obstructive pulmonary disease (COPD), gained EU regulatory approval in December as *Onbrez Breezhaler*. This product has demonstrated greater improvements in lung function, breathlessness and quality of life compared to current therapies and will be the first new inhaled compound in Europe for treatment of COPD in more than seven years. In the US, Novartis met with the FDA in November to discuss a Complete Response letter received in October in which the FDA requested additional information on the dosing proposed for QAB149. Novartis is working with the FDA to review already submitted data to determine what, if any, further clinical trials would be required.

- **Tekturna/Rasilez** (aliskiren) is the first and only approved direct renin inhibitor, available for treating high blood pressure. It is now approved in more than 80 countries and is the basis for single-pill combination products. A combination of aliskiren with the calcium channel blocker amlodipine was filed in the US and is on track to be filed in the EU in 2009, and a triple-combination therapy with aliskiren, amlodipine and a diuretic is expected to be filed in 2010. Results from the exploratory AVANT-GARDE study, which is part of the ASPIRE HIGHER clinical development program, showed no benefit of early inhibition of the renin-angiotensin-aldosterone system (RAAS) in reducing NT-pro BNP, a biomarker for hemodynamic stress, over eight weeks in patients with acute coronary syndrome (ACS).

- **TOBI-TIP** (tobramycin-inhaled powder), a treatment indicated for the long-term management of *Pseudomonas aeruginosa* infections in patients with cystic fibrosis age six years and older, was submitted for EU regulatory approval in December as *TOBI Podhaler*. Clinical trial results showed TIP reduced treatment burden in cystic fibrosis by significantly shortening administration time and reducing the need for nebulisers.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as set, plans, exploring, pipeline, on track, planned, to expand, possible, will, promise, awaiting, strategy, potential, poised, potentially, expected, can, possible, expressions, or by express or implied discussions regarding the potential development and marketing approval of the drugs described in this release, or regarding the potential approval of new indications or labeling for such drugs, or regarding potential future revenues from such drugs. 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 of the new drugs described in this release will be approved for sale in any market. Nor can there be any guarantee that any of the existing drugs will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that any of the drugs described in this release 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; uncertainties involved in the development of new pharmaceutical products; 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 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 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 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: December 9, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
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