NOVARTIS AG
Form 6-K
February 05, 2002

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 for the month of January 2002

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 _

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 X

Enclosures: Releases regarding:

1. FDA Advisory Committee recommends approval of Novartis drug Zometa(R)for the treatment of cancer-related bone complications (January 31, 2002);

2. Study shows Exelon(R)(rivastigmine) beneficial for patients with subcortical vascular dementia (January 28, 2002);

3. International consensus meeting confirms Levodopa as the most effective treatment for Parkinson's disease (January 24, 2002);

4. Novel irritable bowel syndrome (IBS) therapy Zelmac(R)approved in Australia (January 22, 2002);

5. New publication underscores efficacy and safety of Lescol(R)/lescol(R)XL (January 17, 2002);

6. Novartis Animal Health enters US farm-animal vaccine market through two acquisitions (January 17, 2002);

7. Early positive Glivec(R) data in newly diagnosed chronic myeloid leukemia (CML) study prompt major protocol changes (January 7, 2002).

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- Investor Relations Release -

FDA Advisory Committee recommends approval of Novartis drug Zometa(R) for the treatment of cancer-related bone complications

Basel, 31 January 2002 - Novartis announced today that the Oncologic Drugs Advisory Committee (ODAC) of the US Food and Drug Administration (FDA) recommended approval of Zometa(R) (zoledronic acid) for the treatment of bone complications (metastases) associated with a broad range of tumor types. These include prostate cancer, lung cancer, and other tumor types for which no intravenous bisphosphonate therapy is currently approved for treatment, as well as breast cancer and the osteolytic lesions associated with multiple myeloma. Zometa offers patients and clinicians a highly effective treatment with a convenient 15-minute infusion time.

"Novartis is pleased that ODAC has recognized the favorable results of Zometa in the treatment of bone metastases in a broad range of tumor types and has recommended its approval," said David Parkinson, MD, Vice President, Clinical Research at Novartis Oncology. "Based on extensive experience, we believe that Zometa offers significant benefit for helping cancer patients manage this painful and debilitating aspect of their disease."

The FDA generally follows the recommendations of its Advisory Committees although it is not obliged to do so. Novartis submitted the new drug application (NDA) for the use of Zometa in these indications to the US FDA on 22 August 2001 and, on 23 October 2001 the NDA received a priority review designation. Submission to the EMEA in the European Union was made on 30 July 2001.

Clinical Data
The NDA for Zometa is based on data from three large international clinical trials evaluating more than 3,000 patients with myeloma, breast cancer, prostate cancer, lung cancer and other solid tumors. This is the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of a

bisphosphonate in treating cancerous bone lesions.

About Zometa
ZOMETA is a new generation intravenous (IV) bisphosphonate. Novartis has previously received marketing clearance for Zometa in the treatment of hypercalcaemia of malignancy (HCM), also known as tumor-induced hypercalcaemia (TIH), in the European Union and more than 60 countries, including the United States, Switzerland, Brazil, Canada and Australia.

Contraindications and Adverse Events
In clinical trials in patients with bone metastases, Zometa was generally well tolerated with a safety profile similar to other bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough,

dyspnoea and edema. Occasionally, patients experienced electrolyte and mineral disturbances, such as low serum phosphate, calcium, magnesium and potassium.

Bisphosphonates, including Zometa, have been associated with reports of renal function deterioration. Patients who receive Zometa should have periodic evaluations of standard laboratory and clinical parameters of renal function. Doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes. Zometa should only be used during pregnancy if the potential benefit justifies the risk to the fetus. 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.

This release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "recommended approval," "highly effective," "we believe," "potential," "favorable results," and "offers significant benefit," or similar expressions, or by discussions of strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. Some of these are uncertainties relating to unexpected regulatory delays, further clinical trial results regarding efficacy or safety of Zometa, government regulation or competition in general, as well as factors discussed in the Company's Form 20F filed with the 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 described herein as anticipated, believed, estimated or expected.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Study shows Exelon(R)(rivastigmine) beneficial for patients with subcortical vascular dementia

Supports possible future application for Exelon use beyond current indication for Alzheimer's disease

Basel, 28 January 2002 - Exelon(R) (rivastigmine) improves various aspects of mental functioning and behavior in individuals with subcortical vascular dementia, according to a study1 presented today at the Second International Congress on Vascular Dementia in Salzburg, Austria. Exelon is currently approved for treatment of mild to moderate Alzheimer's disease, and is under investigation for the treatment of vascular dementia.

"This is the first study to evaluate the safety and efficacy of Exelon in patients with subcortical vascular dementia, a condition for which there are currently few therapeutic options," said Rita Moretti, MD, lead author of the study and a Neurologist at Cattinara Hospital at the University of Trieste in Italy. "These initial findings are very promising because they showed that Exelon provided broad, significant and sustained improvements in these patients, and also reduced stress levels among the patients' caregivers," she said.

Subcortical vascular dementia is one of the major types of vascular dementia which is due to poor blood circulation in the subcortical area of the brain. It refers to a decline in mental functioning that interferes with the ability to perform routine activities. Vascular dementia is the second most common cause of dementia, accounting for about 20 percent of all cases by itself and up to another 20 percent in combination with Alzheimer's disease. Alzheimer's disease is the leading cause of dementia, accounting for about 50 percent of all cases. Vascular dementia usually affects people between the ages of 60 and 75 and is slightly more common in men than in women.2

In the study, ten men and six women diagnosed with subcortical vascular dementia were randomly assigned to be treated with either Exelon (3 mg/day, increased to 6 mg/day over 4 weeks) or cardioaspirin for 22 months (results after 12 months have previously been reported3). At the beginning and end of the study, patients were given a variety of standard tests to assess various aspects of cognitive function, the ability to perform daily living activities, behavioral symptoms (e.g., mood, delusions and hallucinations), caregiver stress level, and side effects.

By the end of the study, the Exelon group showed significant improvement in "executive function," a type of cognitive function related to the ability to plan and organize, and in behavioral symptoms, compared to baseline ($p < 0.01$

and p <0.05, respectively) and compared to the control group (p <0.001 and p <0.01, respective the lower stress levels among their caregivers by the end of the study (p <0.05 vs. baseline, p <0.01 vs. caregivers of control patients). On average, all the other measures were maintained at baseline levels among patients given Exelon. By contrast, control patients showed no improvements on any of the tests, and showed significant deterioration over baseline in executive function and Clinical Dementia Rating (both p <0.05).

"Deterioration in executive function and behavior are cardinal features of subcortical vascular dementia," said Dr. Moretti. "Therefore, assessing them was particularly relevant in this study, and the improvements we observed suggest Exelon is beneficial in treating the disease," she said.

Side effects in both groups were well tolerated, with transitory nausea the most frequently reported in both groups. No patient withdrew from either group before the end of the study and no serious adverse events were reported. No specific or organic cardiac problems were reported. Although patients were allowed to continue any previous medication, no side effects that might be related to drug interactions were reported.

Although its exact causes are not understood, Alzheimer's disease and vascular dementia are associated with a decline in the ability to transmit signals between nerves in the brain, especially those that rely on the neurotransmitter acetylcholine. Exelon is unique because it works in treating Alzheimer's disease by inhibiting the two key enzymes involved in breaking down acetylcholine - acetylcholinesterase and butyrylcholinesterase - thus preventing the breakdown of the neurotransmitter and prolonging its action. Other drugs used to treat Alzheimer's disease, such as donepezil and galantamine, inhibit acetylcholinesterase but not butyrylcholinesterase. Recent research suggests that butyrylcholinesterase may play an increasingly important role in regulating acetylcholine levels as Alzheimer's disease progresses, and that the dual inhibitory action of Exelon may provide greater and more sustained efficacy in treating patients with the disorder.4

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "possible future application", "improves", "is under investigation", "very promising", "significant improvement" "improvements, "suggests", "may provide", or similar expressions. Such forward looking statements 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 are no guarantees that the aforementioned clinical trials will result in the commercialisation of any product in any market. Any such commercialisation can be affected by, amongst other things, uncertainties relating to product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the 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 described herein as anticipated, believed, estimated or expected.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

International consensus meeting confirms Levodopa as the most effective treatment for Parkinson's disease

Meeting also concludes that use of COMT inhibitors may enhance levodopa benefits

Basel, 24 January 2002 - The world's leading experts in Parkinson's disease (PD) agree that levodopa therapy is deservedly unchallenged as the most effective treatment for the distressing symptoms of PD. Introduced in the 1960s, levodopa represents the cornerstone of PD therapy, and all patients receive this medication at some point during the course of their disease.

Speaking from the international levodopa consensus meeting held on 17th-18th January 2002 in Zurs, Austria, Professor Yves Agid, a leading neurologist and head of neurology at the Hospital de la Salpetriere, Paris, France said "We have been impressed by the evidence presented at this international consensus meeting, which confirms once again that levodopa is still the most effective PD therapy available today. Furthermore, the increasing evidence that the problems previously associated with levodopa therapy can now be resolved, will allow physicians to prescribe levodopa with confidence and ensure that it continues to be the mainstay of treatment for many years to come."

A panel of 28 internationally renowned neurologists and neuroscientists met in Austria to discuss the role of levodopa in clinical practice where all experts unanimously agreed that levodopa fully deserves it's place as the gold standard of therapy for the treatment of PD. In the past, levodopa therapy has been

compromised by a series of complications that include involuntary movements and motor complications. Evidence was presented that the mechanism responsible for these complications relate not so much to levodopa itself, but rather to the way in which it is administered. Recent studies strongly indicate that new ways of delivering levodopa, including the use of a COMT inhibitor, reduces the risk of developing motor complications in animal studies, and this may be the same in humans.

Scientists also discussed the potential of levodopa to be toxic and concluded that, while levodopa can be toxic in some in vitro models, an increasing number of studies suggest it may confer neuroprotection.

Commenting on the main conclusions from this meeting, Professor Fabrizio Stocchi, Director of the Parkinson's Disease Research, Vincenza, Italy said "In the past 4 years, since the last consensus meeting, we have significantly advanced in our understanding of the mechanisms underlying the effects of levodopa. There is now clinical evidence that a more continuous, phsiological delivery of levodopa can reverse motor complications. It appears that one of the ways to achieve this is by using a combination of levodopa with a COMT inhibitor."

This release contains certain "forward-looking statements", relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as "may enhance", "unchallenged", "will allow", "continues", "gold standard", "indicate", reduces the risk", "may be", "it appears", suggest" or

similar expressions. Such forward looking statements 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. Such statements reflect the current views of the meeting with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Some of these are uncertainties relating to clinical trials and product development, unexpected regulatory delays or government regulation generally, and obtaining and protecting intellectual property, as well as factors discussed in the Group's Form 20-F filed with the 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 described herein as anticipated, believed, estimated or expected.

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Orion Pharma is a research and development-orientated pharmaceutical division of the Orion Group. The Orion Group (HEX:ORI) is one of the leading companies in the healthcare sector in the Nordic area of Europe. The 2000 net sales of the Group were EUR 948 million. The Orion Group employs around 5,300 people. Pharmaceutical R&D at Orion Pharma produce new innovative drugs in four core therapy areas: CNS therapies, cardiology and critical care, hormonal therapies,

and respiratory therapies. Entacapone, a COMT enzyme inhibitor, is Orion Pharma's patented molecule discovery, which Orion Pharma developed through multinational clinical trials. Entacapone is available globally as Comtess and Comtan. For further information please consult http://www.orionpharma.com.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Novel irritable bowel syndrome (IBS) therapy Zelmac(R)approved in Australia

Basel, 22 January 2002 - Novartis announced today that the Australian Therapeutics Goods Administration has granted marketing authorization for Zelmac(R) (tegaserod), the first medication clinically proven to provide symptomatic relief for women with abdominal pain/discomfort and constipation associated with irritable bowel syndrome (IBS).

"The approval of Zelmac in Australia is very encouraging and will provide timely access to a much needed therapy for patients suffering from the chronic, debilitating symptoms of IBS" said Nicholas J. Talley, Professor of Medicine, University of Sydney. "I am optimistic that this product will significantly improve the daily quality of life of thousands of Australian women."

The prevalence of IBS in Australia ranges from 10-20%,1 with two thirds of sufferers being female. Zelmac is the first single effective therapy available in Australia to treat the multiple symptoms of IBS, which include abdominal pain/discomfort, and constipation.

"The approval of Zelmac in Australia is yet another milestone in our ongoing commitment to launch this product globally," said Thomas Ebeling, CEO, Novartis Pharma AG. "We believe this approval will serve as additional positive evidence of the safety and efficacy profile of Zelmac to health authorities in other countries, as we continue to negotiate with their regulatory bodies."

About Zelmac
Zelmac is approved in Switzerland and in several Latin American countries including Mexico, Argentina, Venezuela and Columbia. Novartis continues to work with the U.S. Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMEA) to help bring the benefits of this important new therapy to patients in need.

Clinical Data
The approval of Zelmac in Australia is based on clinical trials involving more than 4,500 patients. Throughout the trials two-thirds of patients treated with Zelmac experienced overall symptom relief, including improvements in abdominal pain/discomfort, bloating and constipation.2 The majority had relief within one

week.3 The drug was well tolerated with an adverse event profile similar to that of placebo, with the exception of headache and diarrhea, which in most cases was mild and transient.4,5 Discontinuations based on adverse events were 6.4 % for the Zelmac treated group compared with 4.6 % for the placebo group in the final trial.2

The foregoing press release contains certain forward-looking statements related to the business of Novartis, which can be identified by the use of forward-looking terminology such as "encouraging", "will provide", "will soon be launched", "continues", "ongoing", or similar expressions. Such forward-looking statements 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. Management's expectation regarding the commercial potential of tegaserod in any market could be affected by, amongst other things, uncertainties relating to product development, regulatory actions or

delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company's Form 20F filed with the 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 described herein as anticipated, believed, estimated or expected.

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

New publication underscores efficacy and safety of Lescol(R)/Lescol(R)XL

Basel, 17 January 2002 - Lescol(R)/Lescol(R) XL (fluvastatin), the cholesterol-lowering drug from Novartis, offers a particularly favourable efficacy/safety profile according to a large-scale analysis of CPK (creatine phosphokinase) safety data published in this month's American Journal of Cardiology(1). Based on an analysis of all the Lescol studies conducted by Novartis from 1987 to 2001 and involving nearly 9000 patients, the report confirms that Lescol/Lescol XL as monotherapy is highly effective in lowering blood lipids, and has a CPK safety profile similar to that of placebo (inactive treatment).

"This is a key finding", said co-author Dr Jonathon Isaacsohn, Cincinnati, Ohio. "Statins have proved generally well tolerated and have a favourable safety profile, but there may be significant differences between them. Our analysis of CPK elevations in these clinical trials shows that Lescol/Lescol XL has a very favourable safety profile, similar to that of placebo. No cases of rhabdomyolysis were observed."

Importantly, a previous pooled analysis of three phase-3 studies demonstrated that Lescol/Lescol XL was effective in managing lipid levels, achieving reductions of up to 38% in harmful LDL-cholesterol, and up to 31% in triglycerides, while raising levels of beneficial HDL-cholesterol by up to 21%2. This underscores the drug's favourable efficacy/safety profile in patients who need comprehensive lipid management.

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1 Benghozi et al. Am J Cardiol 2002;89:231-3.

2 Ballantyne et al: Efficacy and Tolerability of Fluvastatin Extended-Relases Delivery System: A Pooled Analysis. Clinical Therapeutics 2001, No 2, Vol 23, p177-192

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MEDIA RELEASE o COMMUNIQUE AUX MEDIAS o MEDIENMITTEILUNG

Novartis Animal Health enters US farm-animal vaccine market through two acquisitions

Basel, 17 January 2002 - Novartis Animal Health today announced that it has acquired Grand Laboratories Inc. and ImmTech Biologics Inc., two US companies specialized in the development, manufacture and marketing of vaccine products for cattle and pigs. The acquisitions provide Novartis with immediate entry into the world's largest farm animal vaccine market, the US. The two businesses generated combined revenues of USD 33 million in 2001. Financial details were not disclosed.

"These acquisitions are strategically linked by strong synergies," said Hans-Beat Gurtler, CEO of Novartis' Animal Health Sector. "Grand Laboratories' well-established manufacturing, registration and marketing capabilities ideally support and enhance ImmTech's state-of-the-art research. The two companies have an exciting development portfolio in important disease areas that are not fully covered by vaccines today," Mr Gurtler added.

Novartis Animal Health has been strategically expanding into the attractive and growing animal vaccine market since 1999, when it bought the British company Vericore. The following year it acquired the Canadian vaccine businesses of Biostar and Cobequid.

Located in Larchwood, Iowa, Grand Laboratories Inc. is one of the largest animal vaccine companies in the US. As a fully integrated business with research, development, manufacturing and marketing capabilities, it offers a broad range of conventional cattle and pig vaccines and has a promising end-stage pipeline

to fuel future growth.

ImmTech Biologics Inc. is a small and innovative animal vaccine company situated in Bucyrus, Kansas, and focused on the development of novel products for cattle and pig rearing. The company holds several proprietary technologies and also has a number of new product introductions pending.

The acquisitions include the production sites and research facilities of both companies, as well as all brands of cattle and pig vaccines for respiratory and enteric diseases. Novartis Animal Health intends to maintain the combined current staff of approximately 230.

The foregoing information contains forward-looking statements that can be identified by terminology such as "promising", "intend" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's expectations regarding future research and development results, or the performance of the acquired companies, could be affected by, among other things, unexpected regulatory delays or government regulation generally; uncertainties relating product development; the introduction of competitive products; changes in the market for animal-based products; changes in the company's ability to obtain or maintain patent and other proprietary intellectual property protection and competition in general.

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Novartis Animal Health researches, develops and commercializes leading animal treatments that meet the needs of pet owners, farmers and veterinarians. Headquartered in Basel, Switzerland and present in 40 countries, Novartis Animal Health employs approximately 2000 associates worldwide and achieved sales of CHF 1.08 billion in 2000. For more information, please consult www.ah.novartis.com.

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- Investor Relations Release -

Early positive Glivec(R) data in newly diagnosed chronic myeloid leukemia (CML) study prompt major protocol changes

Basel, 7 January 2002 - In an interim analysis of the ongoing Phase III study comparing Glivec(R) (imatinib)1 to standard therapy (interferon injections plus Ara-C chemotherapy) for initial treatment in newly-diagnosed CML patients, the Glivec arm was found - early on - to demonstrate a substantially higher response. Based on this finding, the Independent Data Monitoring Board (IDMB) has recommended a change in the protocol to enable the patients on standard therapy who have not achieved a major cytogenetic response to switch to Glivec at this time.

The changes to the study protocol as recommended by the IDMB (comprised of independent hematologists and a clinical statistician) are being communicated to investigators and patients beginning 3 January. These changes allow patients on the control arm who have not achieved a major cytogenetic response after one year of treatment with interferon-alpha and cytarabine to switch to Glivec. A cytogenetic response is the disappearance or reduction in the number of cancerous cells. Patient consent forms will be changed to inform patients of the new data, and to urge them to speak with their physicians.

Called the IRIS study (International Randomized study of Interferon vs. STI571), this large, international multicentre Phase III trial is evaluating Glivec vs. the combination of standard interferon and cytarabine as first line therapy in patients with chronic myeloid leukemia. Between June 2000 and January 2001, the ongoing study enrolled 1106 patients in 177 centres across 16 countries. The study was designed to help determine the long-term outcome (including survival) of patients with newly diagnosed CML treated with Glivec in comparison to the combination of interferon-alpha and cytarabine.

The Independent Data Monitoring Board further recommended that a formal, peer-reviewed presentation of the 12-month data results be made to the scientific community at the earliest possible opportunity.

Preliminary results from a different and smaller, single-institution study in newly diagnosed CML patients were presented in December, 2001 at the annual meeting of the American Society for Hematology.* The data from this trial on the use of Glivec in 47 newly diagnosed patients with early chronic phase CML showed that after three months of treatment, 77% (36 patients) had achieved complete or major cytogenetic responses [(Ph