

NOVARTIS AG  
Form 6-K  
January 11, 2010

# 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 11, 2010**

**(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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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):

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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 -**

**Novartis launches schizophrenia treatment Fanapt in the US, offering patients an attractive alternative to existing medications**

- *Fanapt proven effective for the acute treatment of schizophrenia in adults*
- *Fanapt offers patients a proven tolerability profile with discontinuation rates similar to placebo*
- *Schizophrenia is a chronic, severe and disabling mental disorder, affecting 2.4 million Americans*
- *Despite available medications, there remains a need for additional treatment options*

**Basel, January 11, 2010** Novartis announced that Fanap(iloperidone) tablets are now available for use across the US for the acute treatment of schizophrenia in adults. Fanapt is a twice-daily, oral antipsychotic, approved by the US Food and Drug Administration (FDA) in May 2009.

Schizophrenia remains one of the most debilitating and difficult to treat mental illnesses. The launch of Fanapt is important because there is a need for alternative medications for many individuals who are suffering from this disease, said Ludwig Hantson, PhD, Head of Pharma North America, CEO, Novartis Pharmaceuticals Corporation. In clinical trials, Fanapt was shown to be effective for the symptoms of schizophrenia. Fanapt also showed a low incidence of certain side effects, and the percentage of patients who discontinued treatment was similar to that of placebo.

Schizophrenia is a chronic, severe and disabling mental disorder, affecting 2.4 million Americans. People with schizophrenia have varying levels of response and tolerance to available therapies. Despite the severe symptoms of this disorder, as many as 74% of all patients discontinue their medication before completing 18 months of treatment, according to a major National Institute of Mental Health (NIMH) study. In a separate trial, more than a quarter of patients changed their medications within a year, with a mean time to switching of 100 days.

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Fanapt is indicated for the acute treatment of schizophrenia in adults. In clinical trials, treatment with Fanapt resulted in significant improvement in symptoms of schizophrenia compared to patients on placebo as demonstrated on two major scales for measuring the positive and negative symptoms of the disorder.

The most common adverse drug reactions were dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight gain. In clinical trials, discontinuation rates due to side effects for patients on Fanapt and on placebo were similar. The incidence of akathisia, a feeling of inner restlessness often associated with other antipsychotics, was also shown to be similar between placebo and Fanapt up to the maximum dose of 24 mg

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per day. As many as 87% of patients taking Fanapt did not experience weight gain  $\geq 7\%$  of body weight in clinical trials (88% for 10-16 mg doses; 82% for 20-24 mg doses, and 87% for all patients in the trials). Across all short- and long-term studies, the overall mean weight gain from baseline to end of the trial was 2.1 kg or less than five lbs. Additionally, patients did not experience medically important changes in triglyceride and total cholesterol measurements. Fanapt also demonstrated a low incidence that was similar to placebo of the following extrapyramidal symptoms: parkinsonism, dystonia, dyskinesia and bradykinesia.

Individuals with schizophrenia face enormous challenges, and while there is no cure, it can be a manageable illness when a patient has the right medication, said Dr. Peter Weiden, MD, Director of the Psychotic Disorders Program and Professor of Psychiatry at the University of Illinois at Chicago. It is important to have a therapeutic option like Fanapt that can manage symptoms and enable functioning with a rate of akathisia no higher than placebo and without medically relevant changes in triglycerides and total cholesterol levels.

### **About Fanapt**

Fanapt tablets are indicated for the acute treatment of schizophrenia in adults and belongs to a class of medications for schizophrenia known as atypical antipsychotics.

The FDA approval of Fanapt was supported by two placebo- and active-controlled short-term (4- and 6-week) trials. Safety data was derived from more than 2,000 patients in short- and long-term studies. Both trials enrolled patients who met the DSM-III/IV criteria for schizophrenia. Fanapt was shown to be superior to placebo in controlling symptoms of schizophrenia using the Positive and Negative Symptom Scale (PANSS) and the Brief Psychiatric Rating Scale (BPRS). Efficacy was demonstrated across doses of 12 mg to 24 mg per day which is the recommended daily target dose range. Fanapt must be titrated slowly from a low starting dose to avoid orthostatic hypotension; titration to the lowest effective dose of 12 mg per day can be achieved in four days with the use of an available titration pack. Fanapt can be administered without regard to meals.

The effectiveness of Fanapt for more than 6 weeks has not been systematically evaluated in clinical trials. Therefore, the physician who elects to use Fanapt for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Novartis has exclusive commercialization rights to the oral formulation of Fanapt in the US and Canada under an agreement with Vanda Pharmaceuticals Inc., as well as exclusive rights to develop and commercialize a long-acting injectable (or depot) formulation of this medicine for these markets.

### **About Schizophrenia**

Schizophrenia is a chronic, severe and disabling mental disorder, characterized by profound disruptions in thinking, affecting language, perception, and the sense of self. It often includes psychotic experiences, such as hearing voices or delusions. Schizophrenia typically begins in late adolescence or early adulthood and affects 2.4 million Americans or 1.1% of the adult population.

### **IMPORTANT SAFETY INFORMATION FOR FANAPT (iloperidone) TABLETS**

**Elderly patients are at an increased risk of death when compared with patients who are treated with a placebo. Fanapt is not approved for the treatment of elderly patients (aged 65 and older) with psychosis related to dementia.**

**Serious Side Effects**

Fanapt may change your heart rhythm (meaning there is more time between heart beats). Heart rhythm changes have occurred in patients taking Fanapt and are a risk factor for serious, even life-threatening medical issues. You should tell your doctor if you have or had heart problems. Call your doctor right away if you feel faint or have unpleasant feelings of irregular or forceful heart

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beats as any of these feelings could be a sign of a rare, but serious side effect that could be fatal.

Very high fever, rigid muscles, shaking, confusion, sweating, or increased heart rate and blood pressure. These may be signs of a condition called neuroleptic malignant syndrome (NMS), a rare but serious side effect which could be fatal.

Abnormal or uncontrollable movements of the face, tongue, or other parts of body may be signs of a serious condition called tardive dyskinesia (TD), which could become permanent.

If you have diabetes or risk factors for diabetes (for example, obesity, family history of diabetes), or you have unexpected increases in thirst, urination, or hunger, your blood sugar should be monitored. Increases in blood sugar levels (hyperglycemia), in some cases serious and associated with coma or death, have been reported in patients taking Fanapt and medicines like it.

Tell your doctor if you have a history of or are at risk for seizures, have liver disease, or if you are pregnant or intend to become pregnant. Tell your doctor about all prescription and nonprescription medicines you are taking, since there are some risks for drug interactions.

Lightheadedness or faintness caused by a sudden change in heart rate and blood pressure when rising quickly from a sitting or lying position (orthostatic hypotension) has been reported with Fanapt.

Decreases in white blood cells (infection-fighting cells) have been reported in some patients taking antipsychotic agents, including Fanapt. Patients with a history of a significant decrease in white blood cell (WBC) count or who have experienced a low WBC count due to drug therapy should have their blood tested and monitored during the first few months of therapy.

Fanapt can increase the level of the hormone prolactin. Tell your doctor if you have signs of high prolactin levels, such as breast enlargement, breast pain, or breast discharge.

Medicines like Fanapt can impact your body's ability to reduce your temperature. You should avoid overheating. You should drink fluids so that you do not become thirsty (dehydrated).

Fanapt and medicines like it have been associated with swallowing problems (dysphagia). If you had or have swallowing problems, you should tell your doctor.

As with many conditions that affect the way you think and feel, thoughts of suicide may occur. If you get these feelings, seek help immediately from your doctor, or local emergency room.

For males, in the rare event you have a painful or prolonged erection (priapism), lasting 4 or more hours, stop using Fanapt and seek immediate medical attention.

Fanapt and medicines like it can affect your judgment, thinking, or motor skills. You should not drive or operate hazardous machinery including automobiles until you know how Fanapt affects you.

**Common Side Effects**

The most common side effects include dizziness, dry mouth, feeling unusually tired or sleepy, stuffy nose, orthostatic hypotension, racing heart beat, and weight gain. The average weight gain in clinical studies was 5 lbs. If you experience any of these symptoms, talk with your doctor.

When taking Fanapt, you should avoid drinking alcohol, and you should not breastfeed.

If you would like more information, talk with your doctor. You can also visit the Fanapt Web site at

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www.Fanapt.com or call Novartis Pharmaceuticals Corporation at: 1-888-NOW-NOVA (1-888-669-6682) Monday-Friday, 8:30 am - 5:00 pm ET.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as "can," or similar expressions, or by express or implied discussions regarding potential future revenues from Fanapt. 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 Fanapt will achieve any particular level of revenue in the future. In particular, management's expectations regarding Fanapt could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 each of 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: January 11, 2010

By: /s/ MALCOLM B. CHEETHAM

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

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