NOVARTIS AG
Form 6-K
October 15, 2009

# 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 October 12, 2009**

**(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:

**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 -**

**Novartis enters into agreement for exclusive US and Canadian rights to Fanapt , an FDA-approved oral therapy for schizophrenia**

- *Fanapt (iloperidone), an antipsychotic therapy, is indicated in US for the acute treatment of schizophrenia in adults, set for US launch in early 2010*

- *Addition of Fanapt will strengthen Novartis psychiatry portfolio and build on history in schizophrenia*

- *Schizophrenia is a chronic, severe and disabling psychiatric disorder estimated to affect more than two million adults in the US and nearly 250,000 Canadians*

- *Rights to Fanapt acquired from Vanda Pharmaceuticals Inc. for upfront payment of USD 200 million; Vanda eligible for milestones and sales royalties*

**Basel, October 12, 2009** Novartis Pharma AG has entered into an agreement for exclusive US and Canadian rights to *Fanapt* (iloperidone), a new oral medication that is approved by the US Food and Drug Administration (FDA) for the acute treatment of adults with schizophrenia. Novartis plans to launch *Fanapt* in the US in early 2010.

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

Schizophrenia is a severe psychiatric disorder that is estimated to affect more than 2 million adults in the US and nearly 250,000 Canadians. *Fanapt* belongs to a class of medication for schizophrenia known as atypical antipsychotics.

Schizophrenia remains one of the most chronic and debilitating of the major psychiatric illnesses, underscoring the need for new treatment options, said Ludwig Hantson, PhD, Head of Pharma North America, CEO, Novartis Pharmaceuticals Corporation. With the launch of *Fanapt* in early 2010, we will broaden our presence in psychiatry and build on the heritage of Novartis in offering innovative treatments for devastating psychiatric diseases.

Novartis was a pioneer in offering *Clozaril*® (clozapine) as the first atypical antipsychotic medication in the 1970s, which was considered a breakthrough for patients with treatment-resistant schizophrenia. Novartis also offers medications for Alzheimer s disease, attention deficit hyperactivity disorder (ADHD), Parkinson s disease and multiple sclerosis.

Vanda completed Phase III clinical trials in 2006 and gained US regulatory approval for this medicine in May 2009.

**Terms of the agreement**

Novartis will make an upfront payment to Vanda of USD 200 million for the exclusive rights to commercialize the oral tablet, which is already approved in the US, in the territory of the US and Canada, as well as to develop and commercialize a depot formulation of *Fanapt* for patients in this territory. Vanda will be eligible for additional payments upon achieving defined development and commercial milestones and will also receive sales royalties. Vanda will retain rights to develop and commercialize *Fanapt* outside the territory of US and Canada, but Novartis has the option to enter into discussions with Vanda to co-commercialize *Fanapt* or receive sales royalties outside this territory. The consummation of the transaction is subject to the receipt of customary regulatory approvals, which are expected by the end of 2009.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as set, will, eligible, plans, option, expected, or similar expressions, or by express or implied discussions regarding the potential consummation of the acquisition of Fanapt by Novartis, potential additional marketing approvals for Fanapt products, Novartis obtaining potential additional marketing rights to Fanapt, or 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 with Fanapt to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the proposed Fanapt acquisition will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Fanapt products will be approved for sale in any additional markets or that Novartis will obtain marketing rights to Fanapt in additional markets. Neither can there be any guarantee that Fanapt will achieve any particular levels 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**

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| Date: October 12, 2009 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |