NOVARTIS AG
Form 6-K
September 10, 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 September 10, 2010

(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**

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- Investor Relations Release -

Novartis announces Russian regulatory approval for Gilenya®, a once-daily oral multiple sclerosis therapy and first in a new class

- *Russia is first country to approve Gilenya for the treatment of relapsing remitting MS, the most common form of the disease*

- *Gilenya is the first disease-modifying treatment in a new drug class and offers significant efficacy with a well-characterized safety tolerability profile*

- *Action from the US Food and Drug Administration (FDA) on Gilenya is expected in September 2010; other submissions under review worldwide*

Basel, September 10, 2010 The Russian health authority, the Federal Service on Surveillance in Healthcare and Social Development, has granted approval for Gilenya® (fingolimod) 0.5 mg once-daily oral therapy for the treatment of relapsing remitting multiple sclerosis (MS). Approximately 85% of patients with MS are estimated to have the relapsing remitting form at the onset of disease(1). Russia is the first country to approve Gilenya, providing a new treatment option offering significant efficacy for patients in the convenience of an oral capsule. Novartis expects to launch Gilenya in Russia in early 2011.

In June, an advisory committee of the US Food and Drug Administration (FDA) unanimously recommended approval of Gilenya and action from the FDA is expected in September 2010. Gilenya is also under review by the European Medicines Agency (EMA) as well as other health authorities worldwide.

Data from one of the largest-ever Phase III clinical trial programs conducted in MS were submitted to support the regulatory submissions. These studies provided evidence of the efficacy of Gilenya in reducing relapses, disability progression and brain lesions in patients with relapsing remitting MS as well as safety data. Gilenya is the first in a new class of compounds called sphingosine 1-phosphate receptor (S1PR) modulators. Gilenya provides selective and reversible retention of lymphocytes in lymph nodes, preserving key immune functions and flexibility in patient management.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, under review, expects, recommended, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Gilenya, or the timing of such approvals, or regarding potential future revenues from Gilenya. 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 Gilenya to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenya will be approved for sale in any market, or at any particular time. Nor can

there be any guarantee that Gilenya will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Gilenya 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; 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 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/relapsing-ms/index.aspx. Accessed September, 2010.

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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: September 10, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting