NOVARTIS AG
Form 6-K
February 25, 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 February 22nd, 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

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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: o **No**: x

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- Investor Relations Release -

Novartis oral multiple sclerosis development compound Gilenia®* (FTY720) granted US priority review status

- *US Food and Drug Administration grants priority review status after accepting US regulatory submission for 0.5 mg once-daily Gilenia (fingolimod)*

- *US and European Union regulatory submissions completed in December 2009 for Gilenia include more than 4,000 patient years of clinical trial data*

Basel, February 22, 2010 Gilenia®* (FTY720, fingolimod) has been granted priority review status by the US Food and Drug Administration (FDA), which accepted the regulatory submission made in December 2009 for this medicine. Once-daily Gilenia (0.5 mg) has the potential to become the first approved oral therapy for the treatment of multiple sclerosis (MS).

The FDA grants priority reviews for investigational medicines that could offer significant advances beyond current treatments or where no adequate therapy exists. As a result of this designation, the standard 10-month FDA review period will be reduced to six months.

Since Gilenia involves a new active ingredient (New Molecular Entity), the FDA is likely to require an Advisory Committee meeting and evaluate the risk management program, which could result in the FDA extending its review at the end of the six-month period in June 2010.

"We welcome the decision granting priority review to Gilenia, which underscores the potential benefits of this medicine to patients," said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. "MS is a leading cause of neurological disability in young adults, particularly in women, and this medicine has the potential to offer real advances in the care of people with MS."

Approximately 4,000 patient years of experience have been gained in MS clinical studies involving Gilenia, with some patients now in their sixth year of treatment. Data from one of the largest-ever Phase III clinical trial programs conducted in MS patients were submitted to support the US and European regulatory submissions, including results of the TRANSFORMS and FREEDOMS studies that were recently published in *The New England Journal of Medicine*(1),(2).

Combined data from these studies provided evidence of the efficacy of Gilenia in reducing relapses, disability progression and brain lesions in patients with the relapsing-remitting form of MS as well as safety data. Approximately 85% of patients with MS are estimated to have the relapsing form at the onset of disease(3).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as priority review, potential, could, will, likely, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Gilenia, or the potential timing of such approvals, or regarding potential future revenues from Gilenia. 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 Gilenia to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenia will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that Gilenia will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Gilenia 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 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 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

(1) The brand name Gilenia has been provisionally approved by the FDA for use in connection with the product, but the product itself has not received marketing authorization or NDA approval from any regulatory authorities.

References

(1) Cohen J. et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. N Eng J Med. Vol.362 No.5, Feb 4, 2010 (printed version).

(2) Kappos L, et al. Placebo-Controlled Study of Oral Fingolimod in Relapsing Multiple Sclerosis. N Eng J Med. Vol.362 No.5, Feb 4, 2010 (printed version).

(3) National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/what-is-ms/index.aspx. Accessed January, 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: February 22nd, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting