NOVARTIS AG
Form 6-K
June 14, 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 June 10, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

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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):

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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 -

FDA advisory committee unanimously recommends approval of Novartis investigational treatment FTY720 to treat relapsing remitting MS

- *Committee voted in favor of approval of FTY720 (fingolimod), as treatment in relapsing remitting multiple sclerosis, affirming the drugs positive benefit/risk profile*

- *FTY720, potentially first in a new class of MS therapy, represents a significant advance as an efficacious oral treatment for people with relapsing remitting MS*

- *Committee recommended post marketing collection of additional safety data and evaluation of a lower dose*

Basel, June 10, 2010 Today, an advisory committee of the US Food and Drug Administration (FDA) recommended approval of FTY720 (fingolimod) for the treatment of patients with relapsing multiple sclerosis, the most common form of the disease. The FDA has the option of seeking the advice of one of its advisory committees as it reviews and decides whether to approve a new treatment. The committee voted unanimously that FTY720 demonstrated substantial efficacy in treating relapsing remitting MS and that safety of the proposed 0.5 mg dose justified approval.

This is an encouraging and important milestone for the MS community, said Dr. Patricia O Looney, Vice President, Biomedical Research at the National Multiple Sclerosis Society. We believe that a treatment that reduces relapses and slows disability progression in a convenient oral formulation could encourage more people with MS to initiate treatment in the course of this life-long disease.

The committee evaluated data from the largest clinical trial program ever submitted to the FDA as part of an MS new drug application. This study data provided evidence of superior efficacy of FTY720 over one of the most commonly prescribed treatments, interferon beta-1a IM (Avonex®), and to placebo, in reducing relapses and brain lesions (a measure of disease activity)(1),(2). In addition, the two-year placebo-controlled study showed FTY720 significantly delayed disability progression(2). The advisory committee discussed monitoring parameters for the therapeutic use of FTY720 and also recommended post-marketing collection of additional safety data and evaluation of a lower dose.

Novartis is pleased by the committee s vote to recommend FDA approval of FTY720 as a treatment that has demonstrated substantial efficacy for relapsing remitting multiple sclerosis. The committee s positive vote affirms the favorable benefit/risk profile of FTY720 and we will work closely with the FDA as it finalizes its review of our new drug application, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. If approved, FTY720 will offer patients an effective treatment in the convenience of a pill and we look forward to making this innovative therapy available for people with MS.

If approved, FTY720 would potentially be the first oral therapy for treating relapsing MS. FTY720 would be the first in a new class of therapies developed for relapsing MS called sphingosine1-phosphate receptor (S1PR) modulators, which work by retaining certain immune cells (lymphocytes) in the lymph nodes, preventing them from reaching the central nervous system and causing damage. This lymphocyte retention is reversible, allowing circulating lymphocytes to regain normal levels if treatment is stopped.

The FDA granted FTY720 priority review status in February 2010, reducing the standard 10-month review to six months. In May, the FDA extended the priority review period by three months to September 2010.

The safety profile of FTY720 has been well studied and includes more than 4,500 patient years of experience, with some patients in their seventh year of treatment. In Phase III studies FTY720-related adverse events included transient, dose-related, generally asymptomatic heart rate reduction and infrequent transient AV conduction block at treatment initiation, mild (1-3 mm Hg) blood pressure increase, macular edema (more common with 1.25 mg than the 0.5 mg target dose), and generally asymptomatic, reversible elevation of liver enzymes(1),(2).

The rates of infections overall, including serious infections, were comparable among treatment groups, although a slight increase in lung infections (primarily bronchitis) was seen in patients treated with FTY720. The number of malignancies reported across the two studies was small with comparable rates between the FTY720 and control groups(1),(2).

Multiple sclerosis is thought to be an autoimmune disease of the central nervous system that is chronic, progressive and often disabling. It affects over 400,000 Americans and up to 2.5 million people worldwide. The most common form of the disease, relapsing MS, is characterized by exacerbations or flare-ups interspersed with periods of disease remission. Typically, MS strikes in early adulthood between the ages of 20 and 40, and affects women twice as frequently as men.

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommends, potentially, recommended, believe, could, recommend, will, look forward. would, priority review, or similar expressions, or by express or impl discussions regarding potential marketing approvals for FTY720 or the timing of any such approvals, or regarding potential future revenues from FTY720. 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 FTY720 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that FTY720 will be approved for sale in any market or at any particular time. Nor can there be any guarantee that FTY720 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding FTY720 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.

References

(1) Cohen J. et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. N Eng J Med 2010; 362:402-415.

(2) Kappos L. et al. A Placebo-Controlled trial of Oral Fingolimod in Relapsing Multiple Sclerosis. N Eng J Med 2010; 352:5.

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