NOVARTIS AG
Form 6-K
June 02, 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 May 25th, 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

Novartis International AG

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- Investor Relations Release -

Novartis announces extension of US regulatory priority review period for FTY720, an investigational once-daily oral multiple sclerosis therapy

- *US Food and Drug Administration (FDA) extends priority review period by three months to September 2010, in line with previously announced expectations*

- *FDA Advisory Committee meeting scheduled for June 10 to review data from FTY720 clinical trial program in MS*

- *FTY720 clinical trial program is largest ever submitted to FDA to support approval of a new medicine in this therapeutic area*

Basel, May 25, 2010 Novartis announced today that the US Food and Drug Administration (FDA) has extended by three months, to September 2010, its review period for the regulatory approval of FTY720 (fingolimod). FTY720 once-daily 0.5 mg has the potential to be the first oral therapy for relapsing multiple sclerosis (MS).

A meeting of the FDA s Peripheral and Central Nervous System Drugs Advisory Committee remains scheduled for June 10, 2010, to discuss the benefit/risk profile of this new active ingredient (New Molecular Entity).

The FDA granted priority review status for FTY720 in February 2010, reducing the standard 10-month review period to six months, which was set to end on June 21, 2010. The extension was based on the FDA s request for further analysis of available data, which Novartis responded to and which triggered the three-month extension. The agency did not ask for additional clinical trials. Priority reviews are granted by the FDA for investigational medicines that could offer significant advances beyond current treatments or where no adequate therapy exists.

The announcement of this revised timeline is in line with our expectations, and reflects the comprehensive clinical program and resulting large amount of data to be reviewed in the NDA, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. MS is a leading

cause of neurological disability in young adults and we are very committed to bringing new therapies to patients with this disabling condition.

Data from the FTY720 MS clinical trial program, the largest ever submitted to the FDA to support approval of a new medicine in this therapeutic area, have demonstrated the significant benefits of FTY720 in reducing relapses in people with MS.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as extension, extends, priority review, scheduled, extended, potential, set, could, expectations, to be, committed, or similar expressions, or by express or implied discussio potential marketing approvals for FTY720, or the potential timing of 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.

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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: May 25th, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting