NOVARTIS AG
Form 6-K
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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 April 15, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

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Form 20-F: x Form 40-F: o

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Yes: o **No**: x

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- Investor Relations Release -

FTY720, a novel oral therapy in development for MS, shows sustained benefits for the majority of patients after three years of treatment

- *Phase II study extension shows 68-73% of patients with multiple sclerosis remained relapse-free after three years of treatment with oral FTY720(1)*

- *New data demonstrate 89% of patients free from active brain lesions the injury caused by MS three years after starting treatment(1)*

- *MS, a devastating disease causing progressive disability, affects 2.5 million people worldwide including many young adults(2)*

- *FTY720 regulatory filings planned before end of 2009 in US and EU*

Basel, April 15, 2008 The investigational oral therapy FTY720 (fingolimod) continues to demonstrate sustained benefits in patients with multiple sclerosis (MS) after three years of treatment, according to new clinical data presented today from an ongoing Phase II study extension(1).

Results showed that 73% of patients who began the study on FTY720 5 mg remained free from relapses after three years, and 68% of those who began the study on FTY720 1.25 mg remained relapse-free(1). The figures after two years of treatment were 77% and 75% respectively(3). On the basis of comparable efficacy and a better safety profile, all patients have been transferred to FTY720 1.25 mg in the study extension.

The 36-month data also showed an average annualized relapse rate of 0.20(1), equivalent to one relapse in five years, while 89% of patients were free of the active brain lesions characteristic of MS as measured by magnetic resonance imaging (MRI)(1) three years after starting treatment.

The results were presented at the 60th annual meeting of the American Academy of Neurology (AAN) in Chicago, USA.

These new data demonstrate the exciting potential for FTY720 to reduce relapse rates in MS patients with a convenient once-daily pill, said Professor Giancarlo Comi, Professor of Neurology at the University Vita-Salute San Raffaele in Milan, Italy. An effective oral treatment would be a significant breakthrough in the management of MS. That is why these results are encouraging because we are seeing substantial benefits of FTY720 maintained over time in this clinical trial.

FTY720 is a novel, once-daily, oral treatment in worldwide Phase III clinical development for the treatment of relapsing-remitting MS, the form of the disease that affects approximately 85% of people diagnosed with MS(4).

More than 2.5 million people worldwide are affected by MS(2), the most common non-traumatic cause of neurological disability in young people(5). Regulatory filings for FTY720 are expected in the US and EU before the end of 2009.

The FTY720 Phase III program is the largest conducted in MS to date, and demonstrates our long-term commitment to the field of MS therapy, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. It is especially encouraging to see that FTY720 continues to demonstrate sustained efficacy by helping the majority of patients to remain free of relapses as the study progresses.

FTY720 has the potential to be the first in a new class of therapies for MS that act on inflammation by modulating sphingosine-1-phosphate receptors (S1P-R), reducing the number of inflammatory immune cells, called lymphocytes, from reaching the brain. In addition, FTY720 reaches the brain and S1P-Rs are present on central nervous system (CNS) tissue, so FTY720 may have a direct beneficial effect on MS within the CNS. This additional potential mechanism of action is supported by new preclinical data being presented at AAN(6),(7).

The Phase II study presented at AAN began with a six-month placebo-controlled phase in which 281 patients with relapsing MS received placebo, FTY720 1.25 mg or FTY720 5 mg once-daily. This was followed by a long-term extension in which all patients took FTY720. At the end of three years, 173 patients were in the extension, which is still ongoing. The study has been conducted in Canada and 10 European countries.

Results from the six-month placebo-controlled trial showed that FTY720 reduced relapse rates by more than 50% compared to placebo(5). Current first-line therapies for MS reduced relapse rates by 30-35% on average in two-year studies(5).

Among patients originally on placebo who converted to active therapy in the extension, 51% were free of relapses at three years(1). The figure at two years was 57%(3).

FTY720 has been generally well tolerated throughout the three years of the Phase II study and its extension, with the most common adverse events being nasopharyngitis, headache, fatigue and influenza(1). Increases in alanine aminotransferase (liver enzymes) were observed in 16% of patients. Dermatological screening of patients was implemented in the extension after a small number of cases of localized skin malignancies were reported.

Novartis continues to study FTY720 in an ongoing, blinded Phase III clinical trial program. This program includes comprehensive monitoring that will further assess and characterize the safety profile of FTY720.

MS is caused by the destruction of myelin, which helps neurons carry electrical signals in the brain(8). The disease causes problems with muscle control and strength, vision, balance, sensation and mental function(8). MS typically presents in relapsing forms involving acute self-limiting

attacks of neurological dysfunction (or relapses) followed by complete or partial restoration of functions.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as planned , potential , would , encouraging expected , commitment , may ,

continues , will , or similar expressions, or by express or implied discussions regarding potential future regulatory filings or marketing approvals for FTY720 or regarding potential future revenues from FTY720. Such forward-looking statements reflect the current views of the Company 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 submitted to regulatory authorities for approval, or will be approved for sale in any market. 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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, 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 AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

1. Comi G et al. Oral FTY720 (fingolimod) in patients with relapsing multiple sclerosis. 3-year extension shows sustained low relapse rate and MRI activity. Abstract presented at 60th annual meeting of American Academy of Neurology, Chicago 12-19 April 2008.
2. National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/who-gets-ms/index.aspx. Accessed March 11, 2008.
3. Kappos L. et al. Oral fingolimod (FTY720) in relapsing MS: 24-month results of the Phase II study. ECTRIMS 2006.
4. National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/what-is-ms/index.aspx. Accessed March 11, 2008.
5. Kappos L et al. Oral Fingolimod (FTY720) for Relapsing Multiple Sclerosis. N Engl J Med 2006;355, p. 1130.
6. Barske C et al. FTY720 (Fingolimod) and S1P-Receptor 1 and 5 specific Agonists Increase the Number of Oligodendrocytes in Vitro. Abstract presented at 60th annual meeting of American Academy of Neurology, Chicago 12-19 April 2008.
7. Schubart A et al. FTY720 suppresses ongoing EAE and promotes a remyelinating environment preventing axonal degeneration within the CNS. Abstract presented at 60th annual meeting of American Academy of Neurology, Chicago 12-19 April 2008.
8. National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/symptoms/index.aspx. Accessed March 11, 2008.

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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: April 15, 2008

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting