

NOVARTIS AG  
Form 6-K  
October 01, 2009

# 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 30, 2009**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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**Form 20-F:** ☒ **Form 40-F:** ☐

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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: ☐ **No:** ☒

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**Novartis International AG**

Novartis Global Communications

CH-4002 Basel

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**- Investor Relations Release -**

**Two-year Phase III study shows Novartis oral MS therapy FTY720 significantly reduces relapses and disability progression**

- *FREEDOMS study shows FTY720 reduced relapse rates by 54-60% compared to placebo, and disability progression by 30-32%(1)*
- *Results build on Phase III TRANSFORMS one-year study showing FTY720 reduced relapses significantly more than interferon beta-1a, a standard of care(2)*
- *Phase III efficacy and safety data confirm positive benefit-risk profile for lower 0.5 mg dose(1) and support planned submissions in US and EU at end of 2009*
- *Future development of FTY720 in relapsing forms of MS to focus on lower 0.5 mg dose*

**Basel, September 30, 2009** Initial results from the two-year Phase III FREEDOMS study show that oral FTY720 (fingolimod) was significantly superior to placebo in reducing both relapses and disability progression in patients with relapsing-remitting multiple sclerosis (MS)(1) – one of the leading causes of neurological disability in young adults(3).

The FREEDOMS study met its primary and secondary endpoints for both the 0.5 mg and 1.25 mg doses, with no significant difference in efficacy between doses. This result builds on previous data showing superior efficacy to interferon beta-1a(2) in TRANSFORMS, the largest head-to-head Phase III study against a standard of care treatment in MS.

In FREEDOMS, FTY720 was generally well tolerated with a lower incidence of adverse events at the 0.5 mg dose than 1.25 mg(1). Regulatory submissions for FTY720, planned in the US and EU at the end of 2009, will seek approval for the lower 0.5 mg dose based on comprehensive Phase III results establishing its positive benefit-risk profile. Future development of FTY720 in relapsing forms of MS will focus on the 0.5 mg dose.

We are proud to have reached this critical milestone in the development of FTY720, a novel oral therapy that has the potential to transform the treatment of this ultimately disabling disease, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. FTY720 0.5 mg therapy offers compelling efficacy on all relevant endpoints compared to both placebo and a standard of care, complemented by extensive safety data.

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Results from the placebo-controlled FREEDOMS study show that FTY720 reduced the relapse rate by 54% for the 0.5 mg dose and 60% for the 1.25 mg dose compared to placebo (both  $p < 0.001$ )(1). In addition, FTY720 reduced the progression of disability by 30% for patients on 0.5 mg ( $p = 0.024$ ) and 32% for those on 1.25 mg ( $p = 0.017$ ) compared to placebo over two years(1). These findings were supported by positive effects on brain lesions as measured by magnetic resonance imaging (MRI) scans.

FREEDOMS is the second of three Phase III studies to report results in the largest development program ever conducted in MS, involving more than 4,000 patients worldwide. Previously reported results from the one-year TRANSFORMS study showed a reduction in relapse rates of 52% and 38% for FTY720 0.5 mg and 1.25 mg respectively compared to interferon beta-1a (both  $p < 0.001$ )(2). FREEDOMS II, currently under way, is a two-year placebo-controlled Phase III study, similar in design to FREEDOMS.

The positive results from the FREEDOMS study confirm the efficacy and safety of fingolimod, and provide important evidence of its effect on disability, said Professor Ludwig Kappos, Chair of Neurology and Research Group Leader in the Department of Biomedicine at the University Hospital in Basel, Switzerland, and the principal investigator of the FREEDOMS study. As an oral therapy, it is clear that fingolimod potentially represents a significant advance in the treatment of MS.

FTY720 has a well-studied safety profile with more than 5,300 patient-years of exposure, including patients now in their sixth year of treatment. Previous data from the development program raised questions about potential side effects including macular edema, melanoma, liver injury, infections, and increased blood pressure. In the FREEDOMS study, at the 0.5 mg dose there were no cases of macular edema or melanoma(1). Reversible and generally asymptomatic liver enzyme elevations were observed more frequently with FTY720 than placebo, and lung infections were also slightly more common(1). Mild elevation in blood pressure was observed with FTY720. No new safety signals were seen in FREEDOMS compared to previous clinical trials. Three patients died during the FREEDOMS study, one on FTY720 1.25 mg and two on placebo. None of the deaths was assessed as being related to the study drug(1).

FREEDOMS (FTY720 Research Evaluating Effects of Daily Oral therapy in Multiple Sclerosis) was a double-blind, placebo-controlled study involving 1,272 patients in 22 countries to assess the efficacy, safety and tolerability of FTY720. The primary endpoint was reduction in annual relapse rate and the key secondary endpoint was reduction in disability progression, defined as an increase from baseline in Expanded Disability Status Scale (EDSS) scores confirmed at three months(1).

FTY720 has the potential to be the first in a new class of MS therapies called sphingosine 1-phosphate (S1-P) receptor modulators. Comprehensive analyses of the FREEDOMS data are ongoing, and detailed results are planned to be presented at a leading scientific congress in 2010.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as planned, future, to focus on, will, potential, potentially, or similar expressions, or by express or implied discussions regarding potential future regulatory submissions or approvals for FTY720 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 submitted or 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; competition in general; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 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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#### **References**

- (1) Novartis. Data on file.
- (2) Cohen J. et al. Oral Fingolimod (FTY720) Versus Interferon Beta-1a in Relapsing-Remitting Multiple Sclerosis: Results from a Phase III Study (TRANSFORMS). Slide deck associated with Oral Presentation at the American Academy of Neurology Annual Meeting 2009. [S21.004].
- (3) Cochrane Database of Systematic Reviews 2001, Issue 4.  
<http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002002/frame.html> (Accessed 29 September 2009).

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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 30, 2009

By: /s/ MALCOLM B. CHEETHAM

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

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