

NOVARTIS AG
Form 6-K
April 30, 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 April 29, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Edgar Filing: NOVARTIS AG - Form 6-K

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: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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: ☐ **No:** ☒

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:** ☒

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

- Investor Relations Release -

New data presented at American Academy of Neurology congress show 80-83% of MS patients on oral FTY720 were relapse-free for one year significantly better than a leading current treatment

- *Additional data from a long-term extension of FTY720 Phase II trial show sustained low relapse rates and no significant change in safety profile between three and four years(1)*
- *US and EU regulatory filings on track for end of 2009*

Basel, April 29, 2009 New Phase III results presented at the American Academy of Neurology (AAN) congress show that 80-83% of patients taking FTY720 (fingolimod)(1), an investigational oral compound for relapsing-remitting multiple sclerosis, remained free of relapses during the one-year study compared to 69% of those on interferon beta-1a(2), an established standard of care(3) (p<0.001).

These data reinforce previous results from the TRANSFORMS study announced in December 2008 showing that the relapse rate at one year was 52% lower in patients taking FTY720 0.5 mg than with interferon beta-1a, or Avonex® (0.16 vs. 0.33 respectively)(2). The relapse rate with FTY720 1.25 mg was 38% lower than with interferon beta-1a (0.20 vs. 0.33, both p<0.001)(2). Full results will be submitted to a peer-reviewed journal in the next few months, with regulatory submissions planned in the US and EU at the end of 2009.

TRANSFORMS is the first Phase III clinical trial to show that oral fingolimod may provide patients with an alternative choice to currently available medications for treating relapsing-remitting multiple sclerosis, said Jeffrey Cohen, MD, lead investigator of the TRANSFORMS study and staff physician at the Cleveland Clinic Mellen Center for Multiple Sclerosis Treatment and Research in Cleveland, Ohio, USA.

Also presented at AAN were longer-term results from an ongoing open-label Phase II extension study (n=155)(1). This showed continued low relapse rates after four years of treatment with FTY720, with no significant change in the safety profile from three to four years(1).

In TRANSFORMS, FTY720 was generally well-tolerated with 87% of FTY720 patients completing the study on treatment(2). The most commonly reported adverse events, seen in more than 10% of patients in all three study arms, were headache, nasopharyngitis and fatigue(2). Adverse events seen in FTY720-treated patients in TRANSFORMS included transient reductions in heart rate at the start of treatment, small increases in blood pressure on average, elevations in liver enzymes (also seen with interferon beta-1a)(2), and a small number of cases of

Edgar Filing: NOVARTIS AG - Form 6-K

macular edema. In terms of serious adverse events, infections, bradycardia and atrioventricular block, malignancies and dyspnea were reported in less than 2% of FTY720-treated patients(2). Following the preliminary

(1) 83% of patients on FTY720 0.5 mg and 80% on FTY720 1.25 mg

release of data in December 2008, a patient who had discontinued FTY720 treatment in August 2008 died from aspiration pneumonia related to a progressive neurological condition in February 2009. The exact nature of the underlying diagnosis is unclear, but viral testing has proved negative, including testing for progressive multifocal leukoencephalopathy (PML). A role for FTY720 could neither be confirmed nor excluded. In general, the safety profile of the FTY720 0.5 mg dose appeared to be better than that of the 1.25 mg dose.

Avonex® is a registered trademark of Biogen Idec.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "on track," "will," "planned," "may," or similar expressions, or by express or implied discussions regarding potential marketing 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 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; 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.

Dr. Cohen is a staff physician at Cleveland Clinic. In the past, Dr. Cohen served as a paid member of a Novartis Scientific Advisory Board.

About Novartis

Novartis AG 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 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 98,000 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). Montalban X et al. Oral Fingolimod (FTY720) Shows Sustained Low Rates of Clinical and MRI Disease Activity in Patients with Relapsing Multiple Sclerosis: 4-year Results from a Phase II Extension. Abstract associated with Poster Presentation at the American Academy of Neurology Annual Meeting 2009. [P06.128].
- (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). Avonex website. <http://www.avonex.com/msavProject/avonex.portal>. Accessed March 25, 2009.

###

Novartis Media Relations

Central media line: +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Åsa Josefsson

Novartis Pharma Communications

+41 61 324 0161 (direct)

+41 79 515 2253 (mobile)

asa.josefsson@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:

Ruth Metzler-Arnold

Pierre-Michel Bringer

John Gilardi

Thomas Hungerbuehler

Isabella Zinck

+41 61 324 7944

+41 61 324 9980

+41 61 324 1065

+41 61 324 3018

+41 61 324 8425

+41 61 324 7188

North America:

Richard Jarvis

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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 29, 2009

By: /s/ MALCOLM B. CHEETHAM

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