NOVARTIS AG
Form 6-K
August 17, 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 August 17, 2009

(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**

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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 -

US FDA approves Extavia® the first in a new portfolio of planned MS therapies from Novartis to help patients with this devastating disease

- *Extavia is branded version of interferon beta-1b, a standard-of-care for multiple sclerosis in the US for more than 16 years(1)*
- *MS affects around 400,000 people in US(2) one of the most common neurological disorders in young adults(3)*
- *FDA approval marks important step forward for Novartis, laying foundation for innovative approach to treatment of MS*

Basel, August 17, 2009 The US Food and Drug Administration (FDA) has approved Extavia® (interferon beta-1b), the first in a new planned portfolio of multiple sclerosis (MS) medicines from Novartis to help patients manage this disease.

Extavia is approved by the FDA for the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations. The therapy is also indicated for patients who have experienced a first clinical episode of MS and have features consistent with the disease as shown by magnetic resonance imaging (MRI)(4).

The same medicinal product as Betaseron®*, Extavia offers patients and physicians a new branded version of interferon beta-1b, a first-line disease-modifying therapy that has been a standard-of-care for MS in the US for more than 16 years(1). Extavia will be marketed by the Pharmaceuticals Division of Novartis.

Interferon is a mainstay of treatment in MS, said Doug Jeffery, MD, Associate Professor at Wake Forest University Baptist Medical Center in Winston-Salem, North Carolina, USA. With the approval of Extavia, patients have another option with a well-established safety and efficacy profile to help manage this disease.

MS is estimated to affect approximately 400,000 patients in the US(2), of whom more than 80% have relapsing-remitting MS(5). MS is one of the most common causes of neurological disability in young adults. It is a chronic autoimmune disease in which the body s immune system

attacks the myelin sheath, or protective tissue surrounding the nerve fibers that carry electrical signals in the brain(6). The destruction of myelin causes problems with muscle control and strength, vision, balance, sensation and mental function(7).

Novartis has been a leader in neuroscience for more than 50 years, having pioneered a number of breakthrough therapies which remain important treatments to this day, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. We are committed to providing new approaches to MS care, and the FDA approval of Extavia marks the beginning of our long-term commitment to the MS community in the US.

Extavia will be available to patients in the US this fall. Along with their prescription for Extavia, patients will be given access to a support program including a nurse helpline, one-on-one injection training and reimbursement support services. Extavia patients will have an autoinjector available to them from Novartis.

MS is unpredictable and can be difficult to manage, said Aaron Miller, MD, Professor of Neurology at Mount Sinai School of Medicine in New York, USA. Support programs are an essential element to help patients and physicians effectively manage this complicated disease.

MS typically presents in relapsing forms involving acute self-limiting attacks of neurological dysfunction (known as exacerbations or relapses), followed by complete or partial restoration of function(6).

Interferon beta-1b has been shown to reduce annualized relapse rates by 34% (p=0.0001)(8), with patients nearly twice as likely to remain relapse-free for more than two years compared to those receiving placebo (31% vs. 16%, p=0.007)(8). In addition, treatment with interferon beta-1b may slow disease progression(9). After two years, almost three-quarters of patients who experienced a single episode of neurological disease lasting 24 hours or more did not progress to clinically definite MS(10).

In the European Union Extavia is available in 12 countries and is approved for relapsing-remitting MS as well as early MS (defined as a single demyelinating event with an active inflammatory process) and a steadily worsening form of the disease known as secondary progressive MS with relapses.

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* Novartis gained the rights to seek approval for its own branded version of interferon beta-1b through agreements with Bayer Schering, the company that markets Betaseron.

Betaseron is marketed under the name of Betaferon® outside the US. Betaseron and Betaferon are registered trademarks of Bayer Schering Pharma AG.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as planned, may, committed, long-term commitment, will, can, likely, or similar expressions, or by express or implied discussions regarding potential future multiple sclerosis products or regarding potential future revenues from Extavia or other multiple sclerosis products. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any additional Novartis multiple sclerosis products will be approved for sale in any market. Nor can there be any guarantee that Extavia or such other products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products 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 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.

References

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(3) Multiple Sclerosis International Federation website. http://www.msif.org/en/about_ms/what_is_ms.html. Accessed August 12, 2009.

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(5) Habermann, T. and Amit K. Ghosh ed. *Mayo Clinic Internal Medicine Concise Textbook.* Florence, KY: Informa HealthCare, 2007.

(6) National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/what-is-ms/index.aspx. Accessed August 12, 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: August 17, 2009

By: /s/ MALCOLM B. CHEETHAM

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