NOVARTIS AG
Form 6-K
January 23, 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 January 22, 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 -

Novartis launches Extavia®, a new therapeutic option to help patients combat devastating symptoms of multiple sclerosis

- *Multiple sclerosis (MS) causes progressive disability and affects 2.5 million people worldwide including many young adults (1)*

- *Extavia offers patients and physicians a new branded version of standard-of-care interferon beta-1b*

- *Approved to treat MS patients from first signs of active disease to more advanced, relapsing forms*

- *Launch marks start of planned long-term partnership between Novartis and MS community*

Basel, January 22, 2009 Novartis has today announced the launch of Extavia®, a new version of the standard-of-care for relapsing forms of multiple sclerosis (MS), providing patients and physicians with an alternative option to help manage this devastating disease.

Extavia, a new branded version of interferon beta-1b, is available initially in Germany and Denmark with other European launches to follow during 2009. It is approved to treat a broad range of patients, from those with early signs of MS to those with more advanced relapsing forms of the disease.

Extavia will provide patients and physicians with an additional option for receiving a mainstay of care in MS, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. This important first step also opens the way for Novartis to build supportive partnerships with the MS community and lays the foundations for providing innovative approaches to MS care.

Extavia is the same medicinal product as Betaferon®*, an interferon beta-1b. This has a well characterised efficacy and safety profile with more than 700,000 patient-years experience(2) and a 17-year track record of clinical use the longest for any interferon beta in the treatment of MS(3).

MS is estimated to affect up to 2.5 million patients worldwide and is one of the leading causes of neurological disability in young adults(1). The disease typically presents in relapsing forms involving acute self-limiting attacks of neurological dysfunction (or relapses), followed by complete or partial restoration of function.

Data have shown that interferon beta-1b produces a 34% reduction in annualized relapse rates ($p<0.001$), and patients are almost twice as likely to remain relapse-free for over two years compared to those on placebo (31% vs. 16%, $p=0.007$)(4). Treatment with interferon beta-1b can also slow disease progression. After two years, nearly three-quarters of patients who had experienced a

single episode of neurological disease lasting at least 24 hours did not progress to clinically definite MS(5).

The launch of Extavia in Europe by the Pharmaceuticals Division of Novartis marks the beginning of a long-term commitment to meet the therapeutic needs of the MS community. This will include the establishment of a support program for Extavia users that will foster cross-communication between patients and their physicians and nurses. In turn, this will lay the foundations for future potential innovations in MS therapy. The rollout of Extavia in key EU countries is expected during the coming months.

Novartis acquired the rights to its own branded version of interferon beta-1b in an agreement with Bayer Schering, the company that markets Betaferon. In backing Extavia, Novartis brings over 50 years of neuroscience expertise and resources to the MS community. This expertise has helped to pioneer early breakthrough treatments for a number of neurological and pathological conditions, some of which remain important therapies to this day.

MS is a chronic autoimmune disease of the central nervous system that causes inflammation and neurodegeneration. Pathology is characterised by the destruction of myelin, which helps neurons carry electrical signals in the brain(6). The disease causes problems with muscle control and strength, vision, balance, sensation and mental function(6).

The beneficial effects of interferon beta are believed to be due to its modulation of the immune system to reduce inflammatory damage. Specifically, interferon beta limits the activation of immune cells that attack myelin, suppresses the production of inflammatory cytokines a type of protein that amplifies the inflammatory response causing damage to myelin and stimulates the production of anti-inflammatory cytokines.

Extavia has been filed with the US Food and Drug Administration for the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations (or relapses). Patients with MS in whom efficacy has been demonstrated include those who have experienced a first clinical episode and have features consistent with MS as shown by magnetic resonance imaging (MRI)(7).

Extavia is administered by subcutaneous (or under the skin) injection. Patients will have the choice of using either a fine (30 gauge) needle for manual injection or a convenient autoinjector.

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* Betaferon® is a registered trademark of Bayer Schering Pharma AG.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as launches, planned, long-term, can, w likely, commitment, future, potential, expected, estimated, believed, or similar expressions, or by express or implied discussions regard potential additional marketing approvals for Extavia, the roll-out of Extavia in potential additional markets, the potential development of

additional MS therapies, or regarding potential future revenues from Extavia or additional MS therapies. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that will be approved for sale in any additional markets. Nor can there be any guarantee that Extavia will be launched in any additional markets. Neither can there be any guarantees that Novartis will successfully develop and bring to market any additional MS therapies. Nor can there be any guarantee that Extavia or such additional therapies will achieve any particular levels of revenue in the future. In particular, management s expectations regarding

Extavia and any such additional MS therapies 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; 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 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 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 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) World Health Organization. Neurology atlas, 2004. Accessed 16 Jan 2009. http://www.who.int/mental_health/neurology/neurogy_atlas_review_references.pdf

(2) FDA approves Betaseron® for use after the first event suggestive of multiple sclerosis [press release]. Wayne, NJ: Berlex: 23 October 2006.

(3) Ebers G, Traboulsee A, Langdon D, Goodin D, Konieczny A. The interferon beta-1b 16-year long-term follow-up study: the results. Presented at the 16th meeting of the European Neurological Society; 27-31 May, 2006.

(4) The IFNB Multiple Sclerosis Study Group. Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. *Neurology.* 1993;43:655-661.

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(6) National Multiple Sclerosis Society website. http://www.nationalmssociety.org/about-multiple-sclerosis/symptoms/index.aspx. Accessed January 12, 2009.

(7) Extavia proposed US Prescribing Information.

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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: January 22, 2009

By: /s/ MALCOLM B. CHEETHAM

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