NOVARTIS AG
Form 6-K
September 16, 2008

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 15, 2008

(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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Yes: o **No: x**

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 receives FDA priority review for Coartem®, potentially the first artemisinin-based combination treatment (ACT) for malaria in the US

- *Coartem achieves high cure rates in studies(1),(2) and since 2001 has helped save an estimated 500,000 lives*
- *Priority review by FDA underscores urgency of stopping malaria a key goal of US President s Malaria Initiative*
- *Working with international community, Novartis has supplied more than 195 million treatments to malaria-endemic countries without profit*

Basel, September 15, 2008 Novartis announced today that the US Food and Drug Administration (FDA) has granted priority review for Coartem® (artemether 20 mg/ lumefantrine 120 mg), the leading artemisinin-based combination treatment (ACT) for malaria worldwide. Recommended by the World Health Organization (WHO) and widely used in Africa, Coartem could become the first ACT approved for use by the FDA.

Priority reviews are granted by the FDA to address urgent unmet health issues. These reduce FDA review time for new drug applications from the standard term of 10 months to just six months, and are granted to drugs offering significant advances beyond current treatments or where no adequate therapy exists.

I am pleased that Coartem has been granted priority review by the FDA, said Dr. Daniel Vasella, chairman and CEO of Novartis. In the fight against malaria, we have supplied 195 million treatments of Coartem without profit, helping to save the lives of close to 500,000 people suffering from Malaria. Now Coartem has the potential to be the first ACT approved in the US.

The US government is at the forefront of the international fight against malaria. The President s Malaria Initiative (PMI), led by the US Agency for International Development (USAID) and the Centers for Disease Control and Prevention (CDC), employs a comprehensive approach of prevention and treatment to reduce African deaths due to malaria. PMI is one of the largest purchasers of ACTs.

ACTs play an important role in the fight against malaria, said Rear Admiral Tim Ziemer, US Malaria Coordinator. We are pleased to learn that Novartis is seeking FDA approval for Coartem, a treatment that has already had an important impact in controlling malaria in Africa.

Nearly 40% of the world s population lives at risk of contracting malaria, which is caused by a mosquito-borne parasite. Each year there are more than one million malaria-related deaths, mostly involving children (3). In Africa alone, one child dies every 30 seconds from malaria (4).

Coartem, a fixed-dose combination of two antimalarials, is a highly-effective three-day malaria treatment that according to studies achieves cure rates of over 96% even in areas of multi-drug resistance (1), (2). Combining two or more malaria drugs has the potential to prevent or delay the development of resistance.

In a unique collaboration with international organizations, Novartis has provided more than 195 million Coartem treatments for public sector use in Africa without profit.

Currently approved in more than 80 countries, including 16 European nations, Coartem is the only fixed-dose ACT that has been approved by internationally-recognized stringent health authorities. In these countries, it is indicated for the treatment of acute uncomplicated infections due to plasmodium falciparum, the most dangerous form of malaria.

The most frequently reported side effects in patients who take Coartem include headache, dizziness, weight loss, weakness, fatigue and nausea.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as priority review , estimated , goal , could commitment , will , seeking , potential , or similar expressions, or by express or implied discussions regarding potential marketing approvals for Coartem or regarding potential future revenues from Coartem. You should not place undue reliance on these statements. 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 Coartem to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Coartem will be approved for sale in any market. Nor can there be any guarantee that Coartem will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Coartem 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; 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 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 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis was named a Super Sector Leader by the Dow Jones Sustainability Index (DJSI) in 2007. In the same year, 66 million patients around the world benefited from Novartis programs valued at USD 937 million. These initiatives range from drug donation and research programs to combat neglected diseases like malaria, tuberculosis and leprosy in developing nations, to patient assistance programs that help cancer patients receive the most innovative and effective treatments available. For further information, please consult http://www.novartis.com.

References

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2. Mueller et al, Efficacy and safety of the six-dose regimen of artemether-lumefantrine for treatment of uncomplicated *Plasmodium falciparum* malaria in adolescents and adults: A pooled analysis of individual patient data from randomized clinical trials; *Acta Tropica* 100 (2006) 41 53.
3. Children and Malaria. World Health Organization Roll Back Malaria Web site. Available at: http://www.rbm.who.int/cmc_upload/0/000/015/367/RBMInfosheet_6.pdf.
4. Malaria Fact Sheet. World Health Organization Website. Available at: http://www.who.int/mediacentre/factsheet/fs094/en/.

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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 15, 2008

By: /s/ MALCOLM B. CHEETHAM

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