NOVARTIS AG Form 6-K August 28, 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 August 27, 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:

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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

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: 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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**Novartis Global Communications** 

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- Investor Relations Release -

NICE final guidance recommends Lucentis® as cost-effective treatment for wet AMD, a leading cause of blindness

- Lucentis is only approved therapy to demonstrate improvement in vision and vision-related function in vast majority of wet AMD patients
- NICE decision secures access to innovative medication for eligible patients with wet AMD in England and Wales

Basel, August 27, 2008 The National Institute for Health and Clinical Excellence (NICE) has recommended Lucent® (ranibizumab) as a cost-effective therapy for all eligible patients with wet age-related macular degeneration (AMD), an eye disease that is the leading cause of blindness in people over the age of 50.

The announcement is an important development for patients because NICE determines access to medicines in England and Wales based on agreed standards of cost-effectiveness. The final guidance comes at the end of a rigorous review which assessed the potential benefits of Lucentis for patients relative to the cost of the medicine.

The final guidance is excellent news for patients with wet AMD who are in need of access to this highly effective treatment, said Mr Winfried Amoaku, Associate Professor of Ophthalmology and Hon Consultant Ophthalmologist (Retinal Specialist), University Hospital, Nottingham, and Vice-President of the Royal College of Ophthalmologists, UK. Wet AMD is a debilitating disease that can rapidly lead to loss of vision and all too often, to loss of independence and quality of life for patients. When fully implemented, the NICE decision will ensure that patients have access to Lucentis for as long as they need to preserve or improve their vision.

Lucentis was developed specifically for use in the eye and is the only approved therapy shown to improve vision and vision-related function in a vast majority of patients with wet AMD. The NICE decision was based on data from clinical trials involving more than 7,000 patients, demonstrating that Lucentis enabled patients to read on average an additional four lines (21 letters) on an eye-chart compared to those receiving no treatment. This benefit was sustained for two years (1),(2),(3).

The review evaluated all medications approved for treating wet AMD in the UK, and heard evidence from health professionals, health economic experts and patient groups.

The final NICE guidance includes a reimbursement scheme under which the first 14 injections in each affected eye will be funded by the UK National Health Service (NHS), while the drug costs for any subsequent Lucentis injections will be reimbursed by Novartis(4).

We are committed to working in partnership with health authorities to ensure that as many patients as possible with wet AMD can benefit from treatment with Lucentis, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. This reimbursement scheme is an important collaboration that will ensure patients living with wet AMD in England and Wales receive the best possible care.

Lucentis has been approved in more than 70 countries and has already received positive health economic assessments in a number of other countries including Australia, Belgium, Canada, France, the Netherlands, Scotland, South Korea and Sweden.

AMD is a degenerative eye disease affecting the macula the central part of the retina at the back of the eye that is responsible for the central vision necessary for everyday activities like reading, driving, telling time or identifying faces. Approximately 25 to 30 million people worldwide are living with the disease, which is a major burden on healthcare systems.

There are two types of AMD: dry and wet. Neovascular or wet AMD accounts for about 15% of all AMD cases, but the majority of vision loss. It is associated with the growth of pathological new vessels under the macula that are fragile and leak fluid and blood. If not treated, scar tissue develops and destroys the macula.

Lucentis is an anti-VEGF (vascular endothelial growth factor) therapy that works by binding to and neutralizing all forms of VEGF-A, a protein that is believed to cause abnormal blood vessel growth and leakage beneath the macula.

Lucentis was developed by Genentech and Novartis Pharma AG. Genentech has the commercial rights to Lucentis in the US, while Novartis has exclusive rights in the rest of the world.

#### Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, committed, believed, o similar expressions, or by express or implied discussions regarding potential additional reimbursement approvals or health economic assessments for Lucentis or regarding potential future revenues from Lucentis. 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 Lucentis to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Lucentis will be approved for reimbursement in any additional markets. Nor can there be any guarantee that Lucentis will achieve any particular levels of revenue in the future. In particular, management is expectations regarding Lucentis 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 is 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 is 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.

#### References

- Rosenfeld, PJ et al, for the MARINA Study group. Ranibizumab for Neovascular Age-Related Macular Degeneration. N Engl J Med 2006;355(14):1419-31.
- Brown, D et al, for the ANCHOR Study group. Ranibizumab versus Verteporfin for Neovascular Age-Related Macular Degeneration. N Engl J Med 2006;355(14):1432-44.
- (3) Data on file, Novartis.
- (4) NICE Final Guidance. Ranibizumab and pegaptanib for age-related macular degeneration. At www.nice.org.uk.

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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 27, 2008 By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham Title: Head Group Financial

Reporting and Accounting