

NOVARTIS AG
Form 6-K
January 25, 2007

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 24, 2007

(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: ☒ 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: ☒

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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
[hppt://www.novartis.com](http://www.novartis.com)

- Investor Relations Release -

Lucentis® receives approval in the European Union - the first drug to improve vision in patients with wet AMD, a leading cause of blindness

- ***Lucentis the first and only treatment proven in clinical trials to maintain and improve vision in patients with the degenerative eye disease wet AMD***
- ***Vision improvement with Lucentis treatment increases the ability of patients to perform everyday activities such as reading***
- ***Wet AMD a leading cause of severe vision loss in people over age 50 in the Western world***

Basel, January 24, 2007 - Lucentis® (ranibizumab) has received European Union approval as a new treatment for patients with wet age-related macular degeneration (AMD), a leading cause of severe vision loss in people over age 50 in the Western world.

Until now, available therapies have only been able to slow the decline in vision, not to improve it. Lucentis is the first therapy shown in clinical trials to improve vision and vision-related quality of life in a significant number of people suffering from wet AMD.

The positive European Commission decision for Lucentis is a major breakthrough for the wet AMD community and gives hope to many of us, said MacDonald Curran, Chairman of AMD Alliance International, a non-profit alliance of organizations dedicated to the prevention and treatment of macular degeneration. We now look forward to regulatory authorities in the EU member states continuing to recognize the value of Lucentis by reimbursing it as quickly as possible to avoid unnecessary blindness.

The pivotal studies used in the regulatory submissions for Lucentis and recently published in the *New England Journal of Medicine*[1],[2] show an unprecedented response rate among wet AMD patients. Approximately 95% of Lucentis-treated patients maintained their vision, as defined by a loss of less than 15 letters in visual acuity on the study eye chart. More than 68% of Lucentis-treated patients gained some vision, which is defined as any increase above baseline visual acuity. To date, this gain in vision has been sustained at two years with monthly Lucentis treatment.

The European Commission decision comes just 11 months after submission and applies to all 27 member states as well as Iceland and Norway. Novartis will launch Lucentis in European countries throughout 2007 and 2008.

In addition to the European Union, Lucentis is already approved for use in patients with wet AMD in Switzerland, India and the United States. Novartis expects regulatory decisions in Australia and Canada during the first half of 2007.

With Lucentis, we have a new option for wet AMD patients that offers real hope, said Francesco Bandello, M.D., Full Professor and Chairman of the Department of Ophthalmology at the University of Udine, Italy. Lucentis offers patients the possibility that they will not only gain some vision but also independence by restoring the ability to recognize faces and do day-to-day activities like reading.

Lucentis is designed to block the uncontrolled formation, growth and leakage of new blood vessels underneath the retina that lead to the development of the wet form of AMD and subsequent vision loss. Lucentis is given by intravitreal injection once a month for three months, followed by a maintenance phase in which patients are monitored monthly. Lucentis should be re-administered if a patient loses more than five letters in visual acuity.

After nearly a decade of development, including rigorous clinical trials testing its safety and efficacy, Lucentis is the first treatment to show improvement in vision in a significant number of patients, said James Shannon, M.D., Global Head of Development at Novartis Pharma AG.

Looking into the future, Novartis has clinical trials underway to evaluate the safety and efficacy of Lucentis in other eye diseases, such as diabetic macular edema.

About AMD

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 straight ahead 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.

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 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 look forward to, will launch, hope, possibility, looking into the future, or similar expressions, or by express or implied discussions regarding potential approvals to market Lucentis in additional markets or for additional indications, or potential future sales of Lucentis, or regarding the long-term impact of a patient's use of Lucentis. Such forward-looking statements 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 sale in any additional market, or for any additional indication. Nor can there be any guarantee regarding potential future sales of Lucentis. Neither can there be any guarantee regarding the long-term impact of a patient's use of Lucentis. In particular, management's expectations regarding Lucentis could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data, or new 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; 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 this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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- (1) Rosenfeld PJ, Brown DM, Heier JS, Boyer D, Kaiser P, Chung C, Kim R for the MARINA Study group. Ranibizumab for neovascular age-related macular degeneration: 2-year results of the MARINA study. *N Engl J Med* 355:1419-31, 2006
- (2) Brown DM, Kaiser PK, Michels M, Soubrane G, Heier J, Kim R, Sy J, Schneider S for the ANCHOR Study group. Comparison of ranibizumab and verteporfin photodynamic therapy for neovascular age-related macular degeneration: 1-year results of the ANCHOR study. *N Engl J Med* 355:1432-44, 2006

Media contacts

Corinne Hoff

Novartis Global Media Relations
+41 61 324 9577 (direct)
+41 79 248 5717 (mobile)
corinne.hoff@novartis.com

Matt Meehan

Novartis Pharma Communications
+41 61 324 4879 (direct)
+41 79 592 1813 (mobile)
matt.meehan@novartis.com

e-mail: media.relations@novartis.com

Novartis Global Investor Relations

International:

Ruth Metzler-Arnold	+41 61 324 79 44
Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Jason Hannon	+41 61 324 21 52
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

North America:

Ronen Tamir	+1 212 830 24 33
Arun Nadiga	+1 212 830 24 44
Jill Pozarek	+1 212 830 24 45
Edwin Valeriano	+1 212 830 24 56

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: January 24, 2007

By: /s/ MALCOLM B. CHEETHAM

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