NOVARTIS AG
Form 6-K
October 06, 2006

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 October 5, 2006

(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

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

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

hppt://www.novartis.com

- Investor Relations Release -

Lucentis shows significant vision benefits in pivotal Phase III data published in *New England Journal of Medicine*

- Lucentis the first drug shown to improve vision in patients with wet age-related macular degeneration (AMD), the leading cause of blindness in people over age 60
- Vision benefits of Lucentis sustained in two years of treatment
- Lucentis blocks all biologically active forms of vascular endothelial cell growth factor A (VEGF-A), a molecule believed to be the major underlying cause of wet AMD

Basel, October 4, 2006 Two pivotal Phase III clinical trials (MARINA and ANCHOR) published in *The New England Journal of Medicine* demonstrate that Lucentis® (ranibizumab) treatment maintains or improves vision in patients with wet age-related macular degeneration (AMD), the leading cause of blindness in people over age 60.

The two Phase III, multi-center, randomized, double-masked studies in 1,139 wet AMD patients compared Lucentis treatment to sham control (the MARINA trial) or active control (the ANCHOR trial). Results after two years of treatment (MARINA) and one year (ANCHOR) were published in the US medical journal.

Lucentis has been approved for treatment of wet AMD in Switzerland and the United States, while submission for European Union approval was completed in March 2006.

Results from these studies show that 90% or more of Lucentis-treated wet AMD patients maintained vision, as defined by a loss of less than 15 letters in visual acuity measured on the study eye chart. In addition, up to 40% of patients experienced improvement in vision as defined by a gain of 15 letters or more in visual acuity. Visual acuity refers to the ability of people to detect fine detail or small distances with the eye. The MARINA results demonstrated that vision benefits gained in the first year of the study were maintained with continued treatment in the trial s second year.

After years of rigorous clinical study, Lucentis is the first drug shown to improve vision on average in patients with wet AMD an unprecedented result in the ophthalmology community, said Dr. Gisèle Soubrane, Professor of Ophthalmology at the University Paris XII-Créteil. In addition to clinical benefits, these studies demonstrate that Lucentis is well tolerated. The two-year data show favorable ocular and systemic safety profiles, including the rates of arterial thromboembolic events, which were similar in all treatment groups.

AMD is a degenerative eye disease that affects 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.

There are two types of AMD: dry and wet. 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. These

vessels are fragile and leak fluid and blood, leading to the development of edema as well as scar tissue that destroys the macula.

When wet AMD robs a person of central vision, it also robs them of their independence, said Nicholas Franco, Head of Novartis Ophthalmics. The improvement in vision has been shown to correlate with a return of the ability to do life-affirming everyday activities for these patients, such as reading and shopping. We are excited to make available a drug that improves both vision and vision-related quality of life in patients with wet AMD.

About MARINA and ANCHOR

MARINA is a Phase III, multi-center, randomized, double-masked, sham injection-controlled study of the efficacy and safety of Lucentis in patients with minimally classic or occult subfoveal wet AMD. The primary endpoint was the loss of less than 15 letters in visual acuity at 12 months. The study enrolled 716 patients in the United States who were randomized 1:1:1 to receive 0.3 mg of Lucentis, 0.5 mg of Lucentis or a sham injection approximately 240 patients per study arm.

Two-year results from MARINA show that 90% or more of Lucentis-treated patients maintained vision (defined by a loss of less than 15 letters on the Early Diabetic Retinopathy Study [ETDRS] eye chart) compared to 53% of those in the control group. Up to 33% of Lucentis-treated patients improved vision (defined as a gain of 15 letters or more on the ETDRS eye chart) compared to 4% of the control group. Lucentis-treated patients, on average, experienced an increase of 5.4 letters (0.3 mg Lucentis) and 6.6 letters (0.5 mg Lucentis) in mean visual acuity. Patients receiving sham injections, on average, lost 14.9 letters in mean visual acuity.

ANCHOR is a Phase III, multi-center, randomized, double-masked, active treatment-controlled study of Lucentis administered as a monthly intravitreal injection compared with photodynamic therapy (PDT) administered according to label in patients with predominantly classic subfoveal wet AMD. The primary endpoint was the loss of less than 15 letters in visual acuity at 12 months. The study enrolled 423 patients in the United States, Australia and Europe who were randomized 1:1:1 to receive 0.3 mg of Lucentis, 0.5 mg of Lucentis or PDT approximately 140 patients per study arm.

One-year results from ANCHOR show that 94% or more of Lucentis-treated patients maintain vision compared to 64% of patients receiving photodynamic therapy (PDT). Up to 40% of Lucentis-treated patients improve vision compared to 6% of patients receiving PDT. One-year ANCHOR results showed that Lucentis-treated patients, on average, experienced an increase of 8.5 letters (0.3 mg Lucentis) and 11.3 letters (0.5 mg Lucentis) in mean visual acuity. Patients receiving PDT, on average, lost 9.5 letters in mean visual acuity. Preliminary 24-month ANCHOR results are expected in first quarter 2007.

The most common ocular adverse reactions among Lucentis-treated patients included conjunctival hemorrhage, eye pain, vitreous floaters, increased intraocular pressure and intraocular inflammation. Serious ocular adverse events related to the injection procedure occurred in less than 0.1% of intravitreal injections and included endophthalmitis, retinal detachments and traumatic cataracts. Other serious ocular events that occurred more frequently among Lucentis-treated patients compared to control patients occurring in less than 2% of patients included intraocular inflammation and increased intraocular pressure. There were no statistically significant differences between Lucentis-treated patients and control patients in arterial thromboembolic event (ATE) rates, including stroke and myocardial infarction.

About Lucentis®

Lucentis® (ranibizumab) (0.5 mg) maintains and improves vision in people suffering from neovascular, or wet, age-related macular degeneration (AMD). A therapeutic antibody fragment designed specifically for treating conditions of the eye, Lucentis blocks all biologically active forms of vascular endothelial cell growth factor A (VEGF-A), the molecule believed to be a major underlying cause of wet AMD. Lucentis was developed by Genentech and Novartis. Genentech has the commercial rights to Lucentis in the United States, 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 believed, or similar expressions, or by express or implied discussions regarding potential approvals to market Lucentis in additional markets 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. 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 the Company 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 Ophthalmics

With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of age-related macular degeneration, eye inflammation, glaucoma, ocular allergies and other disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. Novartis products are made in Switzerland, France, the United States and Canada.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

# # #

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

4

Novartis Global Investor Relations

International:

Jean-Jacques Charhon, Global Head IR ad interim	+41 61 324 79 44
Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
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

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: October 5, 2006

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