NOVARTIS AG
Form 6-K
March 08, 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 March 6, 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: ý 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:** ý

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:** ý

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:** ý

Enclosures:

Novartis seeks EU approval for Exforge®, a powerful combination of two leading blood pressure medicines in a convenient once-daily tablet (Basel, March 3, 2006)

Novartis seeks European approval of Lucentis® for the treatment of patients with wet age-related macular degeneration (AMD) (Basel, March 2, 2006)

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- Investor Relations Release -

Novartis seeks EU approval for Exforge®, a powerful combination of two leading blood pressure medicines in a convenient once-daily tablet

Exforge a combination of amlodipine and valsartan two of the world s leading blood-pressure-lowering medicines

Addresses significant unmet need for new combination therapies to help seven out of ten people who are not reaching their treatment goals

Potential for best-in-class efficacy based on clinical data showing significant drop in systolic blood pressure

Basel, March 3, 2006 Novartis has submitted for European approval the new treatment Exforge® (amlodipine and valsartan) to help people with high blood pressure the world s most common killer estimated to affect at least 25% of all adults[1] by combining two of the leading blood pressure-lowering medicines in one tablet.

(1) Kearney et al *Lancet* 2005; 365: 217-223

Exforge, a combination of the calcium channel blocker amlodipine and the angiotensin receptor blocker valsartan, has been shown in clinical trials involving more than 5,000 patients to provide powerful blood pressure control with excellent safety and tolerability.[2]

(2) Data on file

Exforge is expected to help patients who struggle with the inconvenience of multiple medications while trying to reach their blood pressure goals. Significant reductions in both systolic and diastolic blood pressure were observed during the clinical trials, which also showed a lower incidence of peripheral edema (fluid retention) versus the use of amlodipine as a monotherapy.[2]

(2) Data on file

Novartis is seeking approval for Exforge for use in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy, and as replacement therapy for patients taking amlodipine and valsartan as a free combination i.e. from separate tablets. A range of Exforge doses are planned to be made available following approval to help people with high blood pressure meet their treatment goals. In addition to the European Union, Exforge is on schedule to be submitted in 2006 for approval in the US as well as in other countries.

About two-thirds of patients currently take two or more drugs to control their blood pressure, said James Shannon, Head of Development, Novartis Pharma AG. This can be very problematic since the burden of having to take multiple pills is one of the main contributors to poor compliance. Exforge offers the powerful efficacy of two very potent drugs, achieving significant blood pressure reductions with good tolerability and the convenience of a single pill.

Data from clinical trials involving Exforge are planned to be released at the American Society of Hypertension meeting in May 2006.

The combination of these highly efficacious and well-tolerated agents in a convenient single tablet is very exciting for patients and doctors, said Professor Luis M. Ruilope, Associate Professor of Internal Medicine, Head of Hypertension Unit, 12 de Octubre Hospital, Madrid, Spain. The dual mechanism of action is likely to provide patients with greater benefits over either therapy alone and should lead to improved compliance.

High blood pressure is the world s most common killer, affecting at least 25% of all adults.[1] Researchers estimate that the disease affects about one billion people globally.[3] High blood pressure affects and damages arteries in the body, which can burden the heart, kidney, brain and other vital organs and blood vessels. Failing to control high blood pressure can cause heart attacks, strokes, heart and kidney failure as well as premature death. An estimated seven out of ten people with high blood pressure fail to reach their blood pressure targets, with many needing multiple agents to maintain their blood pressure goal.[4],[5]

(1) Kearney et al *Lancet* 2005; 365: 217-223

(3) The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December 2003, p2

(4) Brown et al *Journal of Human Hypertension* 2003; 17, 81-86

(5) The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December 2003, p4

This release contains certain forward-looking statements, relating to the Group s business, which can be identified by the use of forward-looking terminology such as likely to provide , should lead , seeking , is expected , are planned to be made available following approval , or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Exforge. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Exforge will be approved for any indications in any market, nor that it will reach any particular sales levels. In particular, management s expectations regarding commercialization of Exforge could be affected by, among other things, additional analysis of Exforge clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company s current Form 20-F on file with the U.S. 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 (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 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 91,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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- Investor Relations Release -

Novartis seeks European approval of Lucentis® for the treatment of patients with wet age-related macular degeneration (AMD)

Lucentis the first investigational therapy to improve vision in patients with wet AMD

EU filing follows US submission by Genentech

Two Phase III studies show Lucentis maintains or improves vision in up to 96% of treated patients

Basel, March 2, 2006 Novartis announced today the submission of Lucentis® (ranibizumab) for European Union approval for the treatment of neovascular age-related macular degeneration (wet AMD), which is the leading cause of blindness in people over age 60 in the western world(1).

The European submission, done under the centralized procedure, is the latest in a series aimed at obtaining approvals for Lucentis worldwide. Novartis also submitted Lucentis for regulatory approval in Switzerland in February.

Lucentis is the first agent to improve vision in patients with wet AMD, setting a new efficacy standard for the treatment of patients with this debilitating disease. We look forward to working closely with regulatory authorities to ensure the availability of Lucentis to patients as quickly as possible, said Nicholas Franco, Global Head of Novartis Ophthalmics. Novartis is committed to maintaining and improving the vision of people suffering from AMD. With Lucentis, we would be able to provide patients with another effective treatment for wet AMD.

The EU submission follows positive one-year clinical data on the efficacy and safety of Lucentis from two pivotal Phase III trials (MARINA and ANCHOR) that demonstrated the ability of Lucentis to maintain or improve vision in nearly all patients treated. In both of the pivotal Phase III trials, Lucentis was shown to maintain or improve vision in up to 96% of patients treated, regardless of baseline lesion type, lesion size or

baseline visual acuity of the patient.

In addition, the recently unmasked two-year efficacy and safety data from the MARINA study are consistent with results observed at one year, showing continued Lucentis treatment sustained the beneficial vision effects achieved during the first year of treatment, while the vision of patients in the sham-control group* continued to decline over time. Results will be presented during ARVO, a medical congress held in Fort Lauderdale, Florida, from April 29 to May 4, 2006.

Lucentis works by inhibiting the growth of abnormal new blood vessels as well as leakage under the macula which lead to wet AMD disease progression and subsequent vision loss.

AMD is estimated to affect over 25 million people worldwide(2). It is caused by growth of abnormal blood vessels also known as choroidal neovascularization (CNV) or ocular angiogenesis under the macula, the part of the retina that is responsible for central vision, required for activities such as reading, recognizing faces and driving. These vessels leak fluid and blood, causing the development of scar tissue that destroys the macula, leading to the loss of central vision over a period of months to years.

While existing agents have been shown to slow the progression of vision loss, there remains a large unmet need for novel therapy options for patients whose independence and quality of life continue to be significantly impacted by this debilitating disease.

About Lucentis

Lucentis (ranibizumab) is a humanized monoclonal antibody fragment designed to bind and inhibit VEGF-A, a protein that is believed to play a critical role in angiogenesis (the formation of and leakage from new blood vessels). Consequently Lucentis blocks abnormal new blood vessel growth and leakiness which leads to wet AMD disease progression and vision loss.

Lucentis is being developed by Genentech and the Novartis Ophthalmics Business Unit. Genentech retains commercial rights for Lucentis in the United States and Canada. Novartis has exclusive commercialization rights for the rest of the world.

About AMD

AMD is a major cause of painless central visual loss and is the leading cause of blindness for people over the age of 60 in the western world(1). It affects over 25 million people worldwide(2). AMD occurs in two forms: dry and wet(1). The dry form is associated with atrophy of the central retina, or macula, that is required for fine vision used for activities such as reading, driving or recognizing faces. The wet form is caused by growth of abnormal blood vessels also known as choroidal neovascularization (CNV) or ocular angiogenesis under the macula. These vessels leak fluid and blood and cause scar tissue that destroys the macula. These changes result in a deterioration of vision over a period of months to years.

The foregoing press release contains certain forward-looking statements that can be identified by terminology such as aimed at , will be , look forward , would be able to or similar expressions, or by express or implied discussions regarding potential marketing approvals of Lucentis, or regarding any potential revenues from Lucentis. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the 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 Lucentis will be approved for sale in any market or that it will reach any particular sales levels. In particular, management s expectations relating to Lucentis could be affected by, among other things, uncertainties relating to clinical trials; unexpected regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; as well as factors discussed in the Company s Form 20-F filed with the US Securities and Exchange Commission. 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 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 diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. Novartis Ophthalmics products are made in Switzerland, France, the United States and Canada. For more information, visit www.novartisophthalmics.com or www.us.novartisophthalmics.com.

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References

(1)National Eye Institute. Age-Related Macular Degeneration: What You Should Know. US Department of Health and Human Services. National Institutes of Health. NIH Publication no.: 03-2294. Available at: http://www.nei.nih.gov/health/maculardegen/webAMD.pdf

(2)AMD Alliance International. Facts About AMD. Available at: http://www.amdalliance.com/AMD_Information/facts_about_amd.html.

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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: March 6, 2006

By: /s/ MALCOLM B. CHEETHAM

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