NOVARTIS AG
Form 6-K
November 21, 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 November 20, 2006

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

Enclosure:

Exforge® receives positive European Union regulatory opinion supporting approval as effective new treatment for patients with high blood pressure (Basel, November 17, 2006)

Lucentis® receives positive European Union regulatory agency opinion for approval as new treatment for a leading cause of severe vision loss (Basel, November 17, 2006)

Novartis to provide additional clarification to EU regulators on data supporting approval of Mycograb® for serious fungal infections (Basel, November 17, 2006)

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Novartis International AG

Novartis Global Communications
CH-4002 Basel
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- Investor Relations Release -

Exforge® receives positive European Union regulatory opinion supporting approval as effective new treatment for patients with high blood pressure

- *Exforge delivers strong blood pressure reductions, even up to 43 mmHg in patients with moderate-to-severe hypertension*

- *Exforge combines complementary actions of valsartan and amlodipine two of the most prescribed branded antihypertension medicines in a single tablet*

- *Clinical trial results show lower incidence of peripheral edema (swelling of the ankles) in Exforge patients compared to those taking amlodipine alone*

Basel, November 17, 2006 Novartis announced today a positive opinion supporting European Union approval of Exforge® (valsartan/ amlodipine besylate) as a new treatment option for patients with high blood pressure.

The Committee for Medicinal Products for Human Use (CHMP) issued the positive opinion for this investigational compound based on data showing efficacy and tolerability of Exforge for the treatment of high blood pressure in a clinical trial program involving 5,000 patients.

Exforge is the first high blood pressure medication to combine the two most commonly prescribed high blood pressure medicines in their classes the angiotensin receptor blocker (ARB) valsartan (Diovan®) and the calcium channel blocker (CCB) amlodipine besylate (Norvasc®).

The European Commission generally follows the CHMP s recommendations and is expected to issue a decision within three months. Novartis plans to make Exforge available to patients in Europe in the April 2007. Exforge has also been submitted for US approval earlier this year, and a decision by the US Food and Drug Administration (FDA) is anticipated in the coming months.

Exforge offers a potential solution to many patients with high blood pressure who currently need two or more medicines to control their illness. This positive opinion for Exforge is highly encouraging since this medicine has been shown to get patients to blood pressure goal with an excellent efficacy and tolerability profile and a reduced pill burden, said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

High blood pressure and its consequences is the world s No. 1 killer, estimated by the American Heart Association to affect one in four adults around one billion people globally. Despite extensive use of current therapies, about 70% of all people with high blood pressure do not reach target blood pressure levels. Many people require two or more medicines to control their blood pressure.

More than 80% of Exforge patients studied reached their recommended blood pressure goals, with reductions in blood pressure of up to 43 mmHg in some groups, according to Phase III data(1) presented at the American Society of Hypertension in May 2006. Exforge also showed a lower incidence of peripheral edema (swelling of the ankles) compared to those taking amlodipine alone.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as, potential solution , is expected , generally follows , plans to , is anticipated , or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Exforge, or potential future revenue from Exforge. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause 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 Exforge will be approved for any indications in the European Union, the United States or any other market, that Exforge will be brought to market in the EU, the US or in any other country, nor that Exforge will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Exforge could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; our 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 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 (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 99,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

Reference

(1.) Comparative safety and blood pressure (BP)-lowering efficacy of a combination of amlodipine + valsartan and lisinopril + hydrochlorothiazide in patients with stage 2 hypertension; ASH 2006

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- Investor Relations Release -

Lucentis® receives positive European Union regulatory agency opinion for approval as new treatment for a leading cause of severe vision loss

- Positive recommendation from the European Union s Committee for Medicinal Products for Human Use (CHMP) comes just nine months after submission
- Lucentis the first drug to improve vision in patients with wet age-related macular degeneration (AMD), setting new treatment standard for this degenerative eye disease
- Vision improvement associated with Lucentis treatment correlates with a return of everyday activities such as reading, driving, telling time or identifying faces

Basel, November 17, 2006 Novartis has received a positive opinion supporting European Union regulatory approval for Lucentis® (ranibizumab) as a new treatment option for patients with the wet form of age-related macular degeneration, the leading cause of severe vision loss in people over age 50 in the western world.

The Committee for Medicinal Products for Human Use (CHMP), which reviews drug applications for all 25 countries in the European Union as well as Iceland and Norway, recommended approval of Lucentis. The European Commission generally follows the recommendation of the CHMP, and delivers its final decision within two to three months.

The positive opinion in Europe came only nine months after submission and comes after earlier approvals for Lucentis in Switzerland, India and the United States. Regulatory submissions for Lucentis have been based on three Phase III clinical trials, including two pivotal studies that were published in October 2006 in the New England Journal of Medicine.

With Lucentis, the future of wet AMD treatment is certainly brighter than ever, said Ursula Schmidt-Erfurth, MD, Professor and Chairman, Department of Ophthalmology, University of Vienna. Lucentis gives real hope to wet AMD patients since it is the first and only therapy proven in clinical trials to help them regain vision on average. This means that many patients may regain the ability to do everyday activities such as reading, driving a car, cooking or going up and down stairs ultimately helping to restore their independence.

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 that are fragile and leak fluid and blood. If not treated, scar tissue develops that destroys the macula.

This positive recommendation highlights the important unmet need in the wet AMD patient population and the fact that Lucentis is a true breakthrough treatment, said Nicholas Franco, Head of Novartis Ophthalmics. Novartis now looks forward to final European Commission approval, and being able to provide European wet AMD sufferers access to Lucentis as quickly as possible.

About Lucentis®

Lucentis® (ranibizumab) has been shown in clinical trials to maintain and improve vision and vision-related quality of life 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 known 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 Pharma AG. Genentech has the commercial rights to Lucentis in the United States, while Novartis Pharma AG has exclusive rights in the rest of the world.

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The foregoing release contains forward-looking statements that can be identified by terminology such as recommended for approval , generally follows , future , may , looks forward to , 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 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 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.

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- Investor Relations Release -

Novartis to provide additional clarification to EU regulators on data supporting approval of Mycograb® for serious fungal infections

- *Committee for Medicinal Products for Human Use (CHMP) issues negative opinion on 2005 Mycograb submission by NeuTec, which was acquired by Novartis in mid-2006*

- *CHMP concluded that Mycograb demonstrated efficacy*; *negative opinion linked to questions about manufacturing and potential implications for product quality and safety*

- *Novartis to provide clarification to EU regulators to support Mycograb approval as a novel treatment for critically ill patients*

Basel, November 17, 2006 Novartis announced today that it plans to submit additional information to the Committee for Medicinal Products for Human Use (CHMP) in Europe to support the approval of Mycograb®, in development as a treatment for life-threatening fungal infections, after the CHMP issued a negative recommendation.

This submission for European Union approval was made in 2005 by the UK biopharmaceuticals company NeuTec Pharma, which Novartis acquired in mid-2006 to expand its portfolio of compounds for hospital-acquired fungal and bacterial infections.

The CHMP opinion was not linked to the efficacy of the compound. The Committee concluded that there was insufficient data relating to the manufacturing and characterization of the product to determine the safety of the compound. Novartis is committed to working with the CHMP to determine appropriate next steps.

Mycograb is a complex biological product produced through microbial fermentation and is produced by third party manufacturers. Novartis is working closely with these manufacturers and the CHMP to provide further clarification and analyses and is confident of gaining regulatory approval. Mycograb had not been submitted for approval in any other country.

Mycograb is a twice-daily intravenous genetically recombinant antibody fragment, or grab, add-on treatment targeting heat shock protein 90 (hsp90) developed for treatment of invasive candidiasis. This life-threatening fungal infection, which is due to the *Candida* species, has a high mortality rate.

In clinical trials, the combination of Mycograb plus amphotericin B demonstrated clear superiority over amphotericin B monotherapy, considered the standard of care. Mycograb binds to the fungal hsp90, disabling the fungal defense mechanism and making fungi more susceptible to medicines such as amphotericin B. Mycograb has been granted Orphan Drug status in Europe and the US for use against invasive fungal infections, including invasive candidiasis.

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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: November 20, 2006

By: /s/ MALCOLM B. CHEETHAM

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