NOVARTIS AG
Form 6-K
October 25, 2010

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 22, 2010

(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

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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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- Investor Relations Release -

Novartis therapy Lucentis® recommended for approval in EU to treat patients with vision loss due to Diabetic Macular Edema, a serious complication of diabetes

- *CHMP positive opinion supports Lucentis approval in EU for treatment in patients with visual impairment due to diabetic macular edema (DME)*

- *Pivotal data shows Lucentis provided rapid, superior and sustained vision gains compared to the current standard of care*

- *Diabetes-associated eye diseases such as DME are a leading cause of blindness in most developed countries in the working-age population*

Basel, October 22, 2010 Novartis has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for Lucentis® (ranibizumab) for the treatment of patients with visual impairment due to diabetic macular edema (DME), a leading cause of blindness in the working-age population in most developed countries.

Lucentis was designed specifically for use in the eye, and its efficacy and safety have now been demonstrated in patients suffering loss of vision due to diabetic macular edema through a robust program of clinical trials, said David Epstein, Division Head of Novartis Pharmaceuticals.

The submission was supported by data from two Novartis-funded clinical trials, RESTORE and RESOLVE, which showed that Lucentis was superior in providing rapid and sustained visual acuity gain versus sham (dummy therapy) or laser therapy, the current standard of care. The RESTORE study showed patients treated with Lucentis alone or with Lucentis plus laser therapy achieved an average 5.9 letters and 5.5 letters gain in visual acuity at 12 months, respectively, compared to laser-treated patients as measured on a standard ETDRS eye chart.

The RESOLVE study showed that Lucentis-treated patients achieved an average 11.7 letters gain in visual acuity at 12 months compared to sham-treated patients, some of whom received laser treatment.

The pivotal data from RESTORE and RESOLVE are further supported by results of an independent US study conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net), showing that at one year nearly 50% of patients eyes treated with Lucentis and laser therapy improved their visual acuity by 10 letters or more, compared to 28% with laser alone. In addition, the study demonstrated superior gains in visual acuity among Lucentis-treated patients up to two years.

Lucentis was generally well tolerated in clinical studies, either when given as monotherapy or when combined with laser treatment. Its safety profile was consistent with that previously reported in large controlled clinical trials, and in rigorous monitoring since Lucentis was first approved for

wet age-related macular degeneration (AMD). Lucentis is currently licensed in more than 85 countries for the treatment of wet AMD.

Diabetic macular edema (DME) is a consequence of diabetic retinopathy the most common diabetic eye complication, characterized by changes in the blood vessels of the retina to the light-sensitive layer at the back of the eye. In patients with DME, leakage from these abnormal blood vessels occurs in the central portion of the retina, called the macula. Because this part of the eye is responsible for sharp central vision, DME can lead to significant visual impairment. Visual impairment due to DME affects approximately 1-3% of patients with diabetes, and DME is a leading cause of blindness in the working-age population in most developed countries.

Lucentis offers an entirely new pharmacological approach to treatment compared to the current standard of care for DME that involves the use of laser burns to stop the capillary leakage and to reduce swelling. Lucentis is an antibody fragment that is injected into the eye and acts by neutralizing vascular endothelial growth factor (VEGF), a protein that is known to increase vascular permeability, resulting in capillary leakage and macular edema in patients with diabetes.

Lucentis was developed by Genentech and Novartis. Genentech has the commercial rights to Lucentis in the United States where Lucentis is also approved for the treatment of macular edema following retinal vein occlusion (RVO). In addition, Genentech is conducting two Phase III studies, RISE and RIDE, in patients with diabetic macular edema. The results are expected in 2011. Novartis has exclusive rights in the rest of the world and plans to file in the European Union for approval of Lucentis for the treatment of visual impairment due to macular edema following RVO.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommended, plans, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Lucentis or regarding potential future revenues from Lucentis. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management 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 submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Lucentis will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Lucentis could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, 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 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 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while

approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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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: October 22, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting