NOVARTIS AG
Form 6-K
March 24, 2011

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 18, 2011

(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

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Yes: o **No**: x

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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 gains positive CHMP opinion for Lucentis® (ranibizumab) to treat vision loss due to macular edema secondary to RVO

- *Lucentis recommended for approval in EU for visual impairment due to macular edema secondary to branch- and central-retinal vein occlusion (RVO)*

- *Pivotal data show rapid and significant improvements in visual acuity at six months with Lucentis treatment compared to standard of care, with gains sustained to 12 months*

- *RVO is a sudden-onset disease where patients suffer from visual impairment and associated difficulties in daily activities such as reading and driving*

Basel, March 18, 2011 Novartis has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for Lucentis® (ranibizumab) to treat patients with visual impairment due to macular edema secondary to retinal vein occlusion (RVO).

Lucentis has been shown to improve vision and vision related quality of life for patients with visual impairment due to macular edema secondary to both branch-RVO (BRVO) and central-RVO (CRVO).

An effective therapy to treathe second most common cause of vision loss due to retinal vascular disease represents a welcome benefit to patients, said Frank G Holz, MD, Professor, Department of Ophthalmology, University of Bonn, Germany. In addition, it is important for physicians to have the option of a well researched therapy like Lucentis.

The recommendation to approve Lucentis was based on data from two Phase III studies in patients with BRVO (BRAVO) and CRVO (CRUISE). These studies showed that approximately 60% of BRVO and 48% of CRVO patients treated with monthly Lucentis gained at least 15 letters of visual acuity at six months, compared with 29% and 17% of those treated according to current standard practice, respectively. Patients maintained their visual acuity gains through to 12 months with as-needed dosing of Lucentis.

We are committed to being a leader in ophthalmology and providing effective licensed therapies that make a difference in people s lives, said David Epstein, Division Head of Novartis Pharmaceuticals. If approved, Lucentis would be the first anti-VEGF therapy licensed for the treatment of RVO in Europe. This would be in addition to the Lucentis approvals for patients with wet age related macular degeneration and patients with vision loss due to diabetic macular edema.

The pivotal data also showed that patients with BRVO experienced a mean gain from baseline of 18.3 letters in visual acuity at month six with monthly Lucentis injections, compared with a gain of 7.3 letters with current standard practice. Patients with CRVO experienced a mean gain from

baseline of 14.9 letters at month six with monthly Lucentis injections, compared with a gain of 0.8 letters with current standard practice.

The safety data from the BRAVO and CRUISE trials were similar to previous studies examining Lucentis, with no new adverse events reported. At six months the most common ocular adverse events that occurred in the Lucentis-treated patients included conjunctival hemorrhage (48%) and eye pain (17%). In the BRAVO trial, there was one case of endophthalmitis, two arterial thrombo-embolic events, fatal hemorrhagic stroke and non-fatal myocardial infarction. One case of non-fatal myocardial infarction was reported in the sham group. In the CRUISE trial, systemic safety events included one case of either myocardial infarction or acute coronary syndrome in each of the three groups. There were no cerebrovascular accidents or deaths.

RVO is usually the result of a blockage forming in a blood vessel in the retina, which is the light-sensitive layer at the back of the eye. In CRVO, the blockage occurs in the main retinal vein at the optic nerve. In BRVO, the blockage occurs in one of the four branches of the main retinal vein. Both CRVO and BRVO can lead to swelling of the macula, which is the central portion of the retina. This swelling of the macula, or macular edema, is the most common cause of visual impairment in patients with RVO. RVO often leads to increased production of vascular endothelial growth factor (VEGF), which can exacerbate the RVO complications.

Laser treatment, the current standard of care for patients with macular edema in BRVO, may provide gradual and partial improvements in visual acuity, though many patients fail to regain vision despite treatment. Laser therapy is not indicated for patients with macular edema in CRVO. Currently, observation is the usual course of action available to these patients.

Lucentis is an antibody fragment that is injected into the eye and acts by neutralizing VEGF. Lucentis is currently licensed in more than 85 countries for the treatment of wet age-related macular degeneration (AMD) and in the European Union for visual impairment due to diabetic macular edema.

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 RVO. 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 recommended, can, may, committed, would, recommendation, expected, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Lucentis, or the timing of any such new indications or labeling, 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 approved for any additional indications or labeling in any market, or at any particular time. 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 regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures, and unexpected reimbursement decisions; 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 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon 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: March 18, 2011

By: /s/ MALCOLM B. CHEETHAM

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