NOVARTIS AG
Form 6-K
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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 June 6, 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

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 gains European Commission approval for Lucentis® to treat vision loss due to macular edema secondary to RVO

- *Lucentis (ranibizumab) is first anti-VEGF approved for visual impairment due to macular edema secondary to branch- and central-retinal vein occlusion (RVO)*

- *Pivotal clinical data show rapid and significant improvements in visual acuity at six months with Lucentis treatment compared with standard of care (P<0.0001), 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, cooking and driving*

Basel, June, 6, 2011 The European Commission has granted Novartis a new indication for Lucentis® (ranibizumab) to treat patients with visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO and central RVO), a sudden-onset disease where patients have difficulties with daily activities such as reading, cooking and driving.

Lucentis becomes the first anti-VEGF therapy licensed for the treatment of both branch- and central-RVO in the European Union, having demonstrated in pivotal trials that it improves vision and vision-related quality of life for these patients.

RVO results from 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 responsible for sharp central vision. 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 RVO complications including macular edema.

This is an important step forward in the management of patients with RVO because the disease is difficult to treat with few available options, said Ian Pearce, Consultant Ophthalmologist, Royal Liverpool University Hospital. Laser treatment can provide partial improvement for BRVO patients but many do not regain their vision. Laser treatment for patients with CRVO is not considered effective and prognosis is worse than that for BRVO.

Approval of Lucentis was based on data from two pivotal Phase III studies, BRAVO in BRVO patients and CRUISE in CRVO patients, that showed early and sustained improvement in vision in patients at six months with monthly Lucentis treatment compared with standard of care, and visual acuity gains were maintained from months seven through 12 with as-needed dosing of Lucentis.

In BRAVO, approximately 60% of BRVO patients treated with monthly Lucentis gained at least 15 letters of visual acuity at six months, compared with 29% of those treated according to current standard practice. Mean gains from baseline in visual acuity at six months were 18.3 letters for BRVO patients, compared with gains of 7.3 letters with current standard practice.

In CRUISE, approximately 48% of CRVO patients treated with monthly Lucentis gained at least 15 letters of visual acuity at six months, compared with 17% of those treated according to current standard practice. Mean gains from baseline in visual acuity at six months were 14.9 letters for CRVO patients, compared with gains of 0.8 letters with current standard practice.

Lucentis has proven to be an important therapy for people with difficult-to-treat eye conditions, including wet age-related macular degeneration and patients with vision loss due to diabetic macular edema, said David Epstein, Division Head of Novartis Pharmaceuticals. Lucentis is the first anti-VEGF therapy available for patients with both BRVO and CRVO. We are very pleased that another group of patients with debilitating vision loss has access to an effective licensed therapy.

Safety data from the BRAVO and CRUISE trials were similar to previous studies with Lucentis in patients with wet AMD and visual impairment due to DME, and no new adverse events were 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.

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 more than 30 countries for the treatment of visual impairment due to diabetic macular edema (DME).

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 can, or similar expressions, or by express or implied discussions 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 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, including unexpected delays or denials with respect to reimbursement; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; government, industry and general public pricing pressures; competition in general, including off-label competition by bevacizumab; 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. 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 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: June 6, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting