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 May 4, 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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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 -

New analysis representing largest available dataset highlights relative safety of Lucentis® (ranibizumab) compared to unlicensed intravitreal Avastin® (bevacizumab)

Basel, May 4, 2011 A new Medicare analysis conducted by Johns Hopkins University presented today at the Association for Research in Vision and Ophthalmology (ARVO) meeting represents the largest available dataset comparing the relative safety of unlicensed intravitreal Avastin® (bevacizumab) and Lucentis® (ranibizumab). These data contribute to the existing body of evidence that suggest that the risk of death and stroke may be higher in patients treated with intravitreal Avastin compared to Lucentis.

Data presented this week at ARVO underscore the importance of drug design with the patient in mind aiming for an appropriate balance of efficacy and safety for a given indication and patient population, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Now more than ever it is clear that Lucentis and Avastin are different, and Novartis believes Lucentis is the best treatment option for patients with wet AMD.

Patient safety, informed consent and full disclosure are major priorities for the AMD Alliance International, said Narinder Sharma, Chief Executive Officer, AMD Alliance International. The Johns Hopkins data gives us valuable additional information that patients and physicians need to consider and discuss when evaluating anti-VEGF treatment for wet AMD patients.

Novartis believes that unlicensed use of drugs should be limited to cases where there is an unmet medical need which cannot be fulfilled by licensed medications.

Additional Information on the analysis

The presentation of the large retrospective cohort analysis conducted by Johns Hopkins University follows the announcement of the CATT (Comparison of Age-related macular degeneration Treatment Trials: Lucentis-Avastin Trial) data. Gower et al from Johns Hopkins University is a retrospective database analysis that includes 77,886 Medicare beneficiaries to compare safety of unlicensed intravitreal Avastin compared to Lucentis in patients with wet age-related macular degeneration (AMD).

Over 10 months, patients with wet age-related macular degeneration treated with unlicensed intravitreal Avastin experienced an 11% increased risk of death and a 57% increased risk of hemorrhagic stroke compared to patients treated with Lucentis. There were no statistically significant

differences in heart attack and ischemic stroke. The author s noted that the analysis suggest differences in the safety profile of Lucentis and unlicensed intravitreal Avastin, though the study was limited by incomplete information on certain factors such as smoking and blood pressure although adjustment for baseline comorbidities and socioeconmic status was performed.

Link to Gower abstract:

http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=3a667d20-f42d-421e-a859-e1b680de80ed&cKey=4e534aee-b678-4b9d-91dc-20a9d6ae0c5

In the one year results of the CATT, unlicensed intravitreal Avastin administered monthly was non-inferior to Lucentis monthly. Lucentis given as needed , which is the treatment regimen registered in the European Union and used by most physicians outside of the United States, was non-inferior to monthly Lucentis. However as needed Avastin failed to meet this endpoint despite a statistically significant higher number of injections. Reductions in retinal thickness and accumulation of fluid in the retina, potential surrogate markers for efficacy, were significantly better with Lucentis, suggesting Lucentis may prove more effective than intravitreal Avastin beyond one year of treatment.

The CATT data also showed numerically more patients on intravitreal Avastin died (Avastin=15, Lucentis=9 at one year) and a significantly higher risk of serious systemic adverse events associated with hospitalizations with unlicensed intravitreal Avastin compared to Lucentis (24.1% vs 19.0%, respectively, p=0.04). As highlighted in the recent *New England Journal of Medicine* report on the CATT results, differences in rates of serious adverse events require further study.

More about Lucentis

Currently, Lucentis is 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). In March 2011, Lucentis received a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO), including both branch- and central-RVO.

Lucentis has a well characterized safety profile and Novartis systematically registers and evaluates the safety and tolerability of Lucentis for licensed indications on an ongoing basis. To date there is more than 750,000 patient-treatment years of exposure globally with Lucentis.

Further, Novartis has launched the LUMINOUS program, one of the largest observational studies in ophthalmology that will provide additional long-term evidence on Lucentis effectiveness and safety in licensed indications in real-life settings.

*Avastin® is a registered trademark of Genentech, Inc

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, aiming, believes, potential, will or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Lucentis, regarding the potential

ultimate findings of studies regarding the safety of Lucentis, or the comparative safety of Avastin and 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 approved for any additional indications or labeling in any market. Nor can there be any guarantees regarding the ultimate outcome of future studies regarding the safety of Lucentis, or regarding the comparative safety of Lucentis and Avastin. Neither 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 study results; 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; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; 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 activities 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:May 4, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting