NOVARTIS AG
Form 6-K
September 06, 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 August 29, 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

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

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- Investor Relations Release -

FDA requests additional clinical data on Novartis drug ACZ885 for the treatment of gouty arthritis

- *Agency issues Complete Response letter requesting more data to support approval; Novartis will continue to work with the FDA on next steps*

- *Novartis remains committed to studying ACZ885 in inflammatory diseases where interleukin-1 beta plays a key role*

Basel, August 29, 2011 Novartis has received a Complete Response letter from the US Food and Drug Administration (FDA) as part of the US regulatory review for ACZ885 (canakinumab) in gouty arthritis patients. In its letter, the FDA requested additional information, including clinical data to evaluate the benefit risk profile in refractory patients.

On June 21, an advisory committee of the FDA voted in favor of the overall efficacy, but recommended that additional retreatment data would be needed to assess the overall safety profile of ACZ885.

Novartis submitted ACZ885 for regulatory review in the EU in 2010 and in the US, Canada and Switzerland in the first quarter of 2011. These submissions were based on clinical trials that showed gouty arthritis patients treated with ACZ885 at the time of an attack experienced superior pain relief at 72 hours and a significant reduction in the risk of new attacks over six months, compared to patients treated with the injectable steroid, triamcinolone acetonide (TA)(1).

ACZ885 was generally well tolerated in these studies, with most adverse events being mild to moderate in severity. Adverse events which included among others infections, were reported more frequently in patients treated with ACZ885 vs. those treated with TA(1).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as committed , will or similar expressions, or by express or implied discussions regarding potential new indications or labeling for ACZ885 or regarding potential future revenues from ACZ885. 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 ACZ885 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee

that ACZ885 will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that ACZ885 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding ACZ885 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; government, industry and general public pricing pressures; competition in general; 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 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Novartis FDA Briefing Book, June 21, 2011.

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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: **August 29, 2011**

By: /s/ MALCOLM B. CHEETHAM

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