NOVARTIS AG
Form 6-K
November 07, 2007

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 November 6, 2007

(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 -

New Galvus® clinical data reinforces efficacy profile; safety update provided to regulatory agencies

New data accepted for publication show Galvus 50 mg twice-daily dose as effective as a thiazolidinedione (TZD), well tolerated and not causing weight gain

Novartis proposes improving Galvus risk/benefit profile through use of approved 50 mg once-daily and twice-daily doses instead of approved 100 mg once-daily

Basel, November 6, 2007 New clinical data involving Galvus® (vildagliptin) has been accepted for publication in the journal Diabetes, Obesity and Metabolism showing this new oral medicine was as effective as one of the leading oral type 2 diabetes treatments and well tolerated.

Separately, Novartis provided on November 6 a safety update to European regulators of pooled data showing numerically less frequent liver enzyme elevations in patients who took either 50 mg per day or 50 mg twice daily of Galvus compared to 100 mg once-daily. As a result, Novartis has proposed changes to European prescribing information recommending use of the already-approved 50 mg once-daily and twice-daily doses instead of the 100 mg once-daily dose. Novartis will discuss the data and recommendations with other regulators.

New clinical data reaffirms effectiveness against a TZD

The results of a new clinical study further confirmed the efficacy of Galvus in combination with metformin, a long-standing oral type 2 diabetes treatment. This trial showed Galvus was as effective as pioglitazone, a member of the thiazolidinedione (TZD) class of diabetes medicines, when each was combined with metformin. Galvus was well tolerated and did not cause the weight gain that often occurs in patients taking a TZD.

In the 24-week study of 576 patients with type 2 diabetes, all of whom had inadequately controlled diabetes despite taking the oral medicine metformin, the addition of a 50 mg twice-daily dose of Galvus to metformin treatment reduced blood sugar levels as effectively as adding a 30 mg once-daily dose of pioglitazone to metformin.

Galvus was shown to be weight neutral, while the addition of the TZD was associated with weight gain (up to 1.9 kg after 24 weeks of treatment).

Novartis provides safety update to regulatory agencies

An updated analysis of pooled clinical trial data involving more than 8,000 patients treated with Galvus was finalized following the European Union approval on September 26 and included recently completed studies.

Novartis will discuss these data with the Committee for Medicinal Products for Human Use (CHMP), which is responsible for the review of medicines in Europe, and will seek a revision of prescribing information before Galvus is launched for sale in European markets.

The recent analysis further characterized a known imbalance in liver enzyme levels, which now appears more visibly in the higher Galvus once-daily dosing regimen. The results showed 0.86% of Galvus patients taking the 100 mg once-daily dose, 0.34% of those taking the 50 mg twice-daily dose and 0.21% of those taking the 50 mg once-daily dose had elevations of the liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT) of greater than three times the upper limit of normal (3xULN).

At a 50 mg daily dosage, the incidence rate was comparable to the 0.20% in the pooled comparator group of about 4,400 patients taking metformin, a TZD, a sulfonylurea or a placebo. The placebo rate was 0.40%, and this was numerically higher than the Galvus 50 mg twice-daily dose. Elevated levels of these enzymes can indicate liver cell damage.

Novartis will continue working with the CHMP and other agencies to review these results and to revise prescribing information for Galvus, which is a member of a new drug class known as DPP-4 inhibitors. The currently approved European information recommends a 50 mg once-daily dose for use in combination with a sulfonylurea as well as a 50 mg twice-daily or 100 mg once-daily dose for combination use with either metformin or a TZD.

Galvus is currently available in Brazil and Mexico as both a 50 mg and 100 mg daily dose. In February 2007, Novartis received an approvable letter from the US Food and Drug Administration (FDA) and is in discussions with the agency.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as proposes , will , approvable , or similar expressions, or by express or implied discussions regarding the potential launch of Galvus for sale in European markets, potential future approvals of Galvus in other countries, including the US, and potential future revenues from Galvus. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Galvus to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that Galvus will be launched for sale in any European market, or that Galvus will be approved in the US or in any other markets. Nor can there be any guarantee that Galvus will achieve any particular levels of revenue. In particular, management s expectations regarding Galvus 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; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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 AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 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: November 6, 2007

By: /s/ MALCOLM B. CHEETHAM

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