NOVARTIS AG
Form 6-K
June 02, 2010

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 27th, 2010

(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 -

Novartis Phase III trial examining EPO906 (patupilone) for patients with advanced ovarian cancer failed to meet primary endpoint

Basel, May 27, 2010 Novartis announced today that patupilone (EPO906) did not show a significant overall survival advantage in a phase III trial of patients with advanced ovarian cancer, refractory or resistant to platinum-based therapy The comparator arm in the trial was Doxil®/Caelyx® (pegylated liposomal doxorubicin).

Investigators involved in the study and regulatory agencies have been notified of the trial outcome. No new or unexpected serious adverse events in the patupilone arm were identified in the trial. Novartis does not plan to proceed with regulatory filings based on these data.

Study details

The Phase III study, conducted in approximately 168 sites in 22 countries, was an open label, active controlled, parallel group, multicenter trial of 829 patients with epithelial ovarian, primary fallopian or primary peritoneal cancer, who were randomized to receive patupilone or Doxil®/Caelyx®. Before enrollment in the trial, patients had received up to a maximum of three prior chemotherapeutic regimens, of which the first was a taxane/platinum therapy. Patients were randomly assigned to intravenous patupilone (10 mg/m(2)) once every three weeks or Doxil®/Caelyx® (50 mg/m(2)) once every four weeks and were evaluated for disease status by Ca-125 and CT scans every eight weeks until disease progression. The primary endpoint of the trial was overall survival. Secondary endpoints included progression-free survival, safety and overall response rate.

About patupilone

Patupilone belongs to a class of microtubule stabilizers called epothilones and is being evaluated in ongoing trials in multiple tumor types, including metastatic colorectal cancer, brain metastases in non-small cell lung cancer (NSCLC) and hormone-refractory prostate cancer (HRPC).

Because it is an investigational compound, the safety and efficacy profile of patupilone has not yet been established. This investigational compound is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of uncertainty of clinical trials, there is no guarantee that patupilone will ever be commercially available anywhere in the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as plan, is being evaluated, potential, will, or similar expressions, or by express or implied discussions regarding potential future regulatory submissions or approvals for patupilone or regarding potential future revenues from patupilone. 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 patupilone to be materially different from any future results,

performance or achievements expressed or implied by such statements. There can be no guarantee that patupilone will be submitted or approved for sale in any market. Nor can there be any guarantee that patupilone will achieve any levels of revenue in the future. In particular, management s expectations regarding patupilone 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; 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 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 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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**Doxil® is a registered trademark of Centocor Ortho Biotech Products L.P.*

Caelyx® is a registered trademark of Schering Plough

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 27th, 2010

By: /s/ MALCOLM B. CHEETHAM

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