

NOVARTIS AG
Form 6-K
March 16, 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 March 16, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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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: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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Yes: ☐ **No:** ☒

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: ☐ **No:** ☒

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- Investor Relations Release -

Exploratory trial shows no incremental benefit of aliskiren add-on therapy in improving changes to cardiac shape in heart attack patients

- *Trial assessed addition of aliskiren to help limit changes to the heart's shape and function in patients after heart attack (post-myocardial infarction)(1)*
- *A small numerical reduction in cardiac volume from adding aliskiren to standard therapy seen in echocardiogram results, but not statistically significant(1)*
- *ASPIRE, an exploratory study, is one of 14 trials in the ASPIRE HIGHER clinical trial program evaluating aliskiren potential benefit beyond blood pressure reduction*

Basel, March 16, 2010 The addition of the cardiovascular medicine aliskiren to standard therapy for patients recovering from a heart attack showed some positive effects in helping limit changes in the heart's shape and function, but did not demonstrate a statistically significant benefit, according to new clinical trial results(1).

Data from the ASPIRE study (Aliskiren Study in Post-MI patients to Reduce rEmodelling) were presented at the American College of Cardiology (ACC) Congress in Atlanta. Results from the study showed that the addition of aliskiren did not provide the anticipated effect of limiting adverse changes to the heart's left ventricle, which is the organ's main pumping chamber that can often reduce its ability to pump blood efficiently(1).

The 36-week study involving 820 patients, all of whom had evidence of impaired left ventricular function, assessed changes in left ventricular end systolic volume (LVESV) through echocardiograms from baseline to the study end. A small numerical reduction in cardiac volume (LVESV, -0.99 mL) was seen in patients receiving aliskiren and standard therapy compared to those given standard therapy only; however, this was not statistically significant(1).

The combined rates of cardiovascular death, hospitalization for heart failure, recurrent heart attack, stroke and resuscitated sudden death were similar in the aliskiren group and the group given standard therapy. In patients receiving aliskiren in addition to standard therapy there was a higher rate of hyperkalemia, hypotension and kidney dysfunction when compared to the group receiving standard therapy alone(1).

Based on the results of this trial, Novartis does not plan to pursue an outcome trial for post-MI patients. SPIRE is one of 14 trials in the 35,000 patient SPIRE HIGHER clinical trial program that is designed to evaluate potential benefit of aliskiren beyond blood pressure reduction.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, plan, potential, or similar expressions, or by express or implied discussions regarding the outcome of the ASPIRE HIGHER clinical trial program, regarding potential new indications or labeling for aliskiren or regarding potential future revenues from aliskiren as a result. 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 aliskiren to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees regarding the potential outcome of the ASPIRE HIGHER clinical trial program. Nor can there be any guarantee that aliskiren will be submitted or approved for any additional indications or labeling in any market. Neither can there be any guarantee that any such additional indications or labeling will result in aliskiren achieving any particular levels of revenue in the future. In particular, management's expectations regarding aliskiren 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; 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, 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>.

References

- (1) Solomon S, et al. Effect of the Direct Renin Inhibitor Aliskiren on Left Ventricular Remodelling Following Myocardial Infarction with Left Ventricular Dysfunction: ASPIRE. Late Breaker presentation at American College of Cardiology 59th Annual Scientific Sessions 2010

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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: March 16, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting
