NOVARTIS AG
Form 6-K
October 03, 2006

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 October 3, 2006

(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

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

hppt://www.novartis.com

- Investor Relations Release -

New four-year results of major trial confirm Femara® significantly cuts risk of breast cancer recurrence and spread after surgery

- ***Femara significantly reduced risk of breast cancer returning, even in women more likely to suffer recurrence***

- ***Four-year efficacy and safety profile in nearly 5,000 patients consistent with two-year analysis no increase in adverse events with longer-term treatment***

- ***Data reveal emerging benefit in women whose cancer was not found in lymph nodes at time of diagnosis***

Basel, October 2, 2006 New four-year data confirm that initial treatment with Femara® (letrozole) following breast cancer surgery provides significantly greater protection from the recurrence and spread of cancer to distant parts of the body than tamoxifen.

Longer-term data comparing two arms of the independent Breast International Group (BIG) 1-98 trial were presented today at the European Society of Medical Oncology congress in Istanbul, Turkey, by Dr. Alan Coates, MD, Clinical Professor in the School of Public Health at the University of Sydney in Australia.

After a median follow-up of more than four years (51 months), postmenopausal women with hormone-sensitive early breast cancer taking Femara had an 18% reduction in their overall risk of breast cancer recurrence and a 19% reduction in the risk of their cancer spreading to another part of the body. Cancer that spreads to other parts of the body increases the likelihood that a woman will die from the disease.

Importantly, the use of Femara resulted in greater disease-free survival in two groups of women who are at particular risk of recurrence those whose cancer had already spread to the lymph nodes at the time of diagnosis (node positive) and those who had received chemotherapy. In these groups, the risk of recurrence was reduced in the study by 23% (p=0.004) and 26% (p=0.03), respectively.

It is great news to see that in patients with more than four years of median follow-up from this important trial, the results clearly confirm earlier findings that letrozole offers these women an effective hormonal therapy to lower the risk of breast cancer returning or spreading after surgery, said Prof. Beat Thürlimann of St. Gallen, Switzerland, and the BIG 1-98 Trial study chair. The data also confirm a consistent safety profile, with no increase in adverse events in patients with longer-term treatment.

For the first time, results from BIG 1-98 also revealed emerging evidence that Femara may benefit women with node negative disease (i.e. those whose cancer is not detected in the lymph nodes at diagnosis). In this group at 51-month median follow-up, Femara reduced the risk of breast cancer coming back by 12% compared to 2% observed at the 26-month median follow-up, although this measure did not reach statistical significance.

The current analysis included nearly 5,000 women assigned to receive five years of continuous Femara or tamoxifen. The primary core analysis conducted after a 26-month median follow-up included women assigned to two other arms of the study, where they received Femara or tamoxifen for two years followed by three years of the other agent.

Longer follow-up data out to more than four years in 5,000 women provide the most compelling evidence to date that Femara helps to protect against breast cancer relapse in postmenopausal women, said Diane Young, Vice President and Global Head of Clinical Development at Novartis Oncology. We are committed to ongoing research that will help define optimal treatment for women with breast cancer.

Femara is the only medicine in its class indicated for women with hormone-dependent breast cancer taken as either initial treatment immediately after surgery or after they have completed five years of tamoxifen therapy (extended adjuvant setting).

Adverse events for both Femara and tamoxifen were consistent with previously reported results from this trial, as well as current Femara prescribing information for adjuvant treatment. The most common side effects experienced by patients taking Femara in the trial were hot flushes, fatigue, joint pain and nausea.

About BIG 1-98

BIG 1-98 is the only clinical trial that incorporates both a head-to-head comparison and a sequencing of Femara and tamoxifen as adjuvant treatment for postmenopausal women with hormone receptor-positive breast cancer. The results of the primary core analysis of the head-to-head comparison based on a median follow up of 26 months were published in the *New England Journal of Medicine* on December 29, 2005. The BIG 1-98 trial was conducted by the International Breast Cancer Study Group (IBCSG) with many independent centers and was supported by Novartis.

About Femara

Femara is a leading once-a-day oral aromatase inhibitor available in more than 90 countries, including the US, major European markets, and Japan. Femara is approved for the following uses (not all indications are available in every country):

- Adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer
- Extended adjuvant treatment of hormone-dependent early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy for five years
- First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer
- For advanced breast cancer in women with natural or artificially induced postmenopausal status after relapse or disease progression who have previously been treated with antiestrogens
- For pre-operative therapy in postmenopausal women with localized hormone-receptor-positive breast cancer which allows subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.

Important safety information

Femara should not be taken if you have previously had any unusual or allergic reactions to letrozole or any of its ingredients. Femara should not be taken by women who are pregnant or breastfeeding. Only women who are postmenopausal should take Femara. Patients with severe liver impairment should be monitored closely. The use of Femara in patients with significantly impaired kidney function warrants careful consideration.

The most common side effects of Femara are hot flushes, fatigue, joint pain and nausea. Other common side effects are anorexia, appetite increase, peripheral oedema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, hair loss, increased sweating, rash, muscle pain, bone pain, arthritis, osteoporosis, bone fractures, weight increase, hypercholesterolemia and depression. Other rare, but potentially serious adverse events include leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis and ischemic cardiovascular disease.

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as new, first time, evidence emerging, show, tend to, yet, help define, or similar expressions, or by express or implied discussions regarding potential new indications, marketing approvals, or future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market, nor that it will reach any particular sales levels. In particular, management s expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; 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; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company s current Form 20-F on file with the U.S. 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, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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Media contacts

Megan Humphrey

Novartis Oncology

+1 862 778 6724 (direct)

megan.humphrey@novartis.com

Corinne Hoff

Novartis Global Media Relations

+41 61 324 9577 (direct)

+41 79 248 5717 (mobile)

corinne.hoff@novartis.com

Novartis Global Investor Relations

International:

Jean-Jacques Charhon	+41 61 324 79 44
Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

North America:

Ronen Tamir	+1 212 830 24 33
Arun Nadiga	+1 212 830 24 44
Jill Pozarek	+1 212 830 24 45
Edwin Valeriano	+1 212 830 24 56

investor.relations@novartis.com

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: October 3, 2006

By: /s/ Malcolm B. Cheetham

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