NOVARTIS AG
Form 6-K
March 12, 2008

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 11, 2008

(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

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Femara® helps protect against return of breast cancer even when treatment starts several years after completing tamoxifen therapy

- *Post-unblinding analysis of MA-17 trial data provides evidence for potential benefit of starting Femara up to seven years after finishing tamoxifen*

- *Femara only member of aromatase inhibitor class with data demonstrating this potential benefit, as published in Journal of Clinical Oncology*

- *Half of all breast cancer recurrences occur five or more years after diagnosis*

- *Separate analysis published in Annals of Oncology affirms significant advantages of Femara when taken after standard tamoxifen therapy*

Basel, March 10, 2008 Women may reduce the risk of their breast cancer returning by starting treatment with Femara® (letrozole) anywhere from one to seven years after finishing tamoxifen therapy, according to a new analysis published today in the *Journal of Clinical Oncology*(1).

The exploratory analysis of post-unblinding results from the landmark MA-17 trial, led by the National Cancer Institute of Canada Clinical Trials Group, evaluated a subset of women in the original placebo group when the study was unblinded.

The analysis shows that women who started Femara several years after completing the recommended five years of tamoxifen reduced their risk of breast cancer coming back by 63% compared to those who did not start Femara(1). In addition, the risk of cancer spreading to other areas of the body was reduced by 61%. The median period before starting Femara was 31 months.

The important message for women is that it may never be too late for many breast cancer survivors to do more to protect themselves against the ongoing risk of disease recurrence, said Paul Goss, M.D., PhD., of the Massachusetts General Hospital in Boston and the lead investigator of MA-17. These data reinforce the need for women diagnosed with breast cancer to go back to their doctors and continue to discuss ways to

reduce their risk of recurrence.

More than 50% of breast cancer recurrences and deaths occur five or more years after completing tamoxifen treatment(1). Femara is the only drug in the aromatase inhibitor class with data showing its potential to reduce the risk of breast cancer returning even when started several years after initial treatment with tamoxifen.

A separate intent-to-treat analysis of unblinded results from the MA-17 trial, published today in the *Annals of Oncology*, supports the significant benefit of initiating Femara within three months of

completing five years of tamoxifen(2). If women do not have the opportunity to begin Femara treatment within three months of completing tamoxifen, the exploratory analysis published in the *Journal of Clinical Oncology* indicates they may still benefit from starting Femara up to several years later.

MA-17 was an international, double-blinded, randomized, multi-center Phase III trial to evaluate the effectiveness of Femara versus placebo in breast cancer survivors who had completed five years of tamoxifen treatment. It was led by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario with funding from the Canadian Cancer Society and support from Novartis.

The trial was unblinded in 2003 after the first planned interim analysis showed a marked benefit for Femara in reducing the risk of breast cancer recurrence(2). At that time, women in the placebo arm were offered the chance to start treatment with Femara or to continue without additional treatment.

The analysis published in the *Journal of Clinical Oncology* evaluated the subset of 2,383 women who were in the placebo group when the MA-17 trial was unblinded. Of these women, 1,579 chose to switch to Femara, while 804 chose not to start Femara. The safety analysis was consistent with many other Femara trials in various treatment settings, reinforcing that Femara is well tolerated.

Novartis has the highest level of commitment to ensuring that women with breast cancer have the knowledge and therapies to reduce their risk of recurrence, whether they were diagnosed yesterday or many years ago, said Diane Young, M.D., Head of Global Medical Affairs at Novartis Oncology. Femara offers protection against recurrence throughout several phases of breast cancer treatment in women with hormone-sensitive early breast cancer. These new data add to the body of clinical evidence for Femara.

The intent-to-treat analysis published in the *Annals of Oncology* evaluated the outcomes for women assigned to Femara and placebo in the original trial study arms. At a median follow-up of 64 months, Femara significantly reduced the risk of breast cancer recurrence by 32% versus placebo. Femara maintained its significant benefit over placebo, even though more than 60% of women in the placebo group started Femara when the study was unblinded.

Results from this analysis affirm the safety and efficacy of Femara as extended adjuvant therapy (i.e. following the completion of five years of tamoxifen).

About Femara

Femara is a leading once-daily oral aromatase inhibitor available in more than 90 countries, including the US, major European countries and Japan. It is approved for a number of indications:

- 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 had prior standard adjuvant tamoxifen therapy for five years
- First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer

- Advanced breast cancer in women with natural or artificially induced postmenopausal status after relapse or disease progression who have been treated with antiestrogens

- Pre-operative therapy in postmenopausal women with localized hormone receptor-positive breast cancer which allows subsequent breast-conserving surgery in patients not originally considered suitable for this type of surgery

Not all indications are available in every country. Subsequent treatment after surgery should be in accordance with the standard of care.

Femara should not be taken by women who 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 edema, 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.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential , may , to be , or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Femara or regarding potential future revenues from Femara. 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 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 or labelling in any market. Nor can there be any guarantee that Femara will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Femara 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, 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Goss PE, Ingle JN, Pater JL, et al. Late extended adjuvant treatment with letrozole improves outcome in women with early-stage breast cancer completing 5 years of tamoxifen. J Clin Oncol. 2008

(2) Ingle1 JN, Tu D. Pater JL , et al. Intent-to-treat analysis of the placebo-controlled trial of letrozole for extended adjuvant therapy in early breast cancer: NCIC CTG MA.17. Annals of Oncology. 2008

# # #

Novartis Media Relations

Beatrix Benz
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 618 7748 (mobile)
beatrix.benz@novartis.com

Megan Humphrey
Novartis Oncology Communications
+1 862 778 6724 (direct)
+1 908 217 5379 (mobile)
megan.humphrey@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International
Ruth Metzler-Arnold
Katharina Ambuehl
Pierre-Michel Bringer
John Gilardi
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis
Isabella Zinck

Central phone no:+41 61 324 7944
e-mail: investor.relations@novartis.com

North America
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: 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: March 11, 2008

By: /s/ MALCOLM B. CHEETHAM

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