NOVARTIS AG
Form 6-K
April 14, 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 April 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

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- Investor Relations Release -

ASA404, a novel cancer agent, begins pivotal trial to explore new approach in treating lung cancer, the leading cause of cancer death

- *With launch of Phase III ATTRACT-1 trial in non-small cell lung cancer, Novartis Oncology assumes responsibility for development of ASA404 from Antisoma*

- *Novel mechanism of action of ASA404 disrupts existing blood supply to tumors*

- *Tumor-Vascular Disrupting Agent is one of six Novartis Oncology compounds in late-stage development for various solid tumors and blood cancers*

Basel, April 11, 2008 Novartis announced today that ASA404, its novel cancer agent, has entered a Phase III lung cancer trial following positive outcomes of a Phase II trial. The novel mechanism of action of ASA404 may represent a new approach to treating the most prevalent cause of cancer death.

ASA404 is a Tumor-Vascular Disrupting Agent (Tumor-VDA) that selectively causes the collapse of existing tumor blood supply leading to extensive tumor cell death. The action of ASA404 is distinct from that of angiogenesis inhibitors, which inhibit the formation of new tumor blood vessels.

In a randomized Phase II study, ASA404, in combination with chemotherapy, demonstrated a median overall survival advantage of more than five months in first-line treatment of advanced non-small cell lung cancer (NSCLC) compared with chemotherapy alone. A similar survival advantage was observed in a subsequent extension of the Phase II study.

Non-small cell lung cancer, the potential lead indication for ASA404, accounts for about 85% to 90% of all lung cancers. Worldwide, lung cancer is the number one cause of death from cancer each year in both men and women, with 1.2 million new cases per year and 921,000 deaths.

With the launch of ATTRACT-1, we look forward to exploring the unique mechanism of action of ASA404 in non-small cell lung cancer to potentially help the more than one million people who develop lung cancer each year, said Alessandro Riva, Executive Vice President and Global Head of Development of Novartis Oncology.

ASA404 is one of six novel oncology compounds Novartis is developing for potential registration over the next five years. The other investigational therapies which focus on a broad array of cancer targets include RAD001 (renal cell carcinoma and other cancers), SOM230 (Cushing s disease/refractory carcinoid tumors, acromegaly), LBH589 (cutaneous T-cell lymphoma and other

cancers), EPO906 (ovarian cancer), and PKC412 (acute myelogenous leukemia and aggressive systemic mastocytosis).

Today, our broad and deep pipeline includes both small molecules and monoclonal antibodies that utilize a variety of mechanisms such as vascular-disruption, anti-angiogenesis, and kinase inhibition to treat cancer, said David Epstein, President and CEO of Novartis Oncology. These exciting potential discoveries have the possibility to change medical treatment for patients suffering with many forms of cancer.

About ATTRACT-1

ATTRACT-1 (Antivascular Targeted Therapy: Researching ASA404 in Cancer Treatment) is a Phase III clinical trial that will be conducted at more than 200 sites in 20 countries.

The trial will be a randomized, double-blind, placebo-controlled, multi-center study of ASA404 in combination with paclitaxel and carboplatin as first-line treatment for locally advanced or metastatic (Stage IIIb/IV) NSCLC of squamous or nonsquamous histology. The trial will consist of 1,200 patients who will be assigned to one of the following treatment arms in a ratio of 1:1: ASA404 1800 mg/m2 plus chemotherapy (carboplatin/paclitaxel) or placebo plus chemotherapy (carboplatin/paclitaxel) as a control. Treatment will be given for up to six cycles, with one cycle equaling 21 days and total treatment equaling 126 days (4.2 months).

ASA404

ASA404 is a small-molecule Tumor-VDA that selectively disrupts existing tumor blood vessels. Solid tumors rely on a network of blood vessels to survive and grow. ASA404 targets existing tumor blood vessels causing death of vessel endothelial cells and the collapse of tumoral blood vessels.

Novartis signed an exclusive licensing agreement with Antisoma plc for the worldwide rights to ASA404 in April 2007.

Because it is an investigational compound, the safety and efficacy profile of ASA404 has not yet been established. Access to 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 ASA404 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 to explore, may, look forward, potential, possibility, will, or similar expressions, or by express or implied discussions regarding potential future approvals to market ASA404 or regarding potential future revenues from ASA404. 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 ASA404 to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that ASA404 will be approved for sale in any market. Nor can there be any guarantee that ASA404 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding ASA404 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; 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.

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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: April 11, 2008

By: /s/ MALCOLM B. CHEETHAM

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