NOVARTIS AG
Form 6-K
October 07, 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 October 6, 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 -

New study shows potential benefits of innovative Xolair® anti-IgE therapy in treating children suffering from moderate-to-severe allergic asthma

- *Results demonstrate that Xolair significantly reduces asthma attacks in children aged six to 11 years(1)*

- *Xolair could offer innovative approach to treating asthmatic children by targeting IgE, a root cause of the symptoms of allergic asthma*

- *Asthma is the most common chronic disease of childhood affecting up to 20% of children in some countries(2); around 78% of cases associated with high IgE(3)*

- *Xolair currently approved for adults and adolescents worldwide submissions to treat children aged six to 11 years are planned*

Basel, October 6, 2008 A new clinical study shows that Xolair® (omalizumab), an innovative treatment for allergic asthma in adolescents and adults, significantly reduced asthma attacks (or exacerbations) in children aged six to 11 years with uncontrolled moderate-to-severe persistent allergic asthma(1).

Asthma is the most common chronic disease of childhood, affecting as many as 10-20% of children in the US, Europe and Australia(2). Up to 78% of these cases are associated with high levels of the immunoglobulin E (IgE) antibody(3), a root cause of allergic asthma.

Xolair is a unique treatment which blocks the action of IgE. By targeting the underlying mechanism of the disease, Xolair can prevent the onset of debilitating symptoms, such as wheezing and shortness of breath, in severely affected patients.

Results of a Phase III study in children were presented today at the annual meeting of the European Respiratory Society (ERS) in Berlin.

The study showed that after 24 weeks, children treated with Xolair suffered 31% fewer clinically significant exacerbations than those receiving placebo or dummy drug (p=0.007)(1). The study therefore met its primary endpoint. Over the entire one-year study, children treated with Xolair suffered 54.2% fewer exacerbations than those on placebo (p<0.001)(1). Xolair was generally safe and well-tolerated in the clinical trial with no differences in adverse events compared with placebo(1).

These data represent an important new approach to treating allergic asthma in children who remain uncontrolled despite their treatment, said Professor Bobby Lanier of the University of North Texas Health Science Center, USA. These children are particularly vulnerable and their lives can be severely affected or even cut short by this disease.

Xolair is approved for adults and adolescents (aged 12 years or above) with moderate to severe persistent asthma in the US, and with severe allergic asthma in the EU. Patients must have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and their symptoms must be inadequately controlled with inhaled corticosteroids. Xolair was approved in the US in 2003 and the EU in 2005, and is now available in 56 countries. Worldwide submissions to treat children aged six to 11 years are planned.

The double-blind, placebo-controlled study presented at ERS assessed the efficacy and safety of Xolair in children aged six to 11 years (n=628) with moderate-to-severe persistent allergic (IgE-mediated) asthma(1). The study comprised a 24-week fixed-dose steroid phase, followed by a 28-week phase in which steroid dose could be reduced and a 16-week safety follow-up period.

Xolair continues to improve the lives of asthma patients across the world, and Novartis is excited about the future opportunity to extend the use of this breakthrough treatment to help younger patients and their families, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG.

Asthma causes children to lose many school-days and may limit their academic achievements and harm social relationships(4). Despite treatment, nearly 497,000 children were hospitalized for asthma in the US alone in 2004(5).

Previous Xolair studies have included 479 children aged six to 12 years. In one Phase III double-blind, placebo-controlled study evaluating Xolair as add-on therapy in children with moderate-to-severe allergic asthma treated with inhaled corticosteroids, Xolair reduced the number of exacerbations, and decreased the use of oral corticosteroids(6).

The results of the studies in children are consistent with earlier clinical trials in adults and adolescents, which showed an average 38% reduction in exacerbations vs. placebo ($p<0.001$) with halving of severe exacerbations and hospitalizations(7).

Xolair, a humanized monoclonal antibody, is administered by a healthcare provider through subcutaneous (under the skin) injection once every two or four weeks. The efficacy of Xolair has already been recognized in international treatment guidelines such as those issued by the Global Initiative for Asthma (GINA), which recommends anti-IgE therapy as add-on treatment for patients with severe allergic asthma that is inadequately controlled by standard clinical options(8).

In clinical studies, the most common side effects in patients receiving Xolair included injection site reactions, viral infections, upper respiratory tract infection, sinus infection, headache, and sore throat. The most serious adverse events reported with Xolair have been anaphylaxis and malignancies. Anaphylaxis, a potentially-life-threatening allergic reaction, has occurred in some patients after they received Xolair. Xolair should always be injected in a doctor s office and patients should be instructed to seek emergency medical treatment immediately if symptoms occur.

Xolair is manufactured by Novartis Pharma AG. In the US, it is co-promoted by Novartis Pharmaceuticals Corporation and Genentech, Inc.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, could, planned, can, future opportunities, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Xolair or regarding potential future revenues from Xolair. You should not place undue reliance on these

statements. 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 Xolair to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Xolair will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Xolair will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Xolair 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; 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 AG 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 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 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1). Novartis. First interpretable results pivotal phase III study CIGE025AIA05. 2008.

(2). von Mutius E, Epidemiology of asthma: ISAAC International Study of Asthma and Allergies in Childhood, Pediatr Allergy Immunol, 1996;7(9 Suppl):54 6.

(3). Peden DB. Development of Atopy and Asthma: Candidate Environmental Influences and Important Periods of Exposure, Environ Health Perspect 108(suppl 3) 2000; 475-482.

(4). World Health Organization. Global surveillance, prevention and control of CHRONIC RESPIRATORY DISEASES. http://www.who.int/gard/publications/GARD%20Book%202007.pdf (accessed 26 August 2008).

(5). Akinbami L. Asthma prevalence, health care use and mortality: United States, 2003-05.

(6). Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2007.

(7). Milgrom H, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (omalizumab). Pediatrics 2001;108:E36.

(8). Humbert M, Beasley R, Ayres J, Slavin R, Hebert J, Bousquet J et al. Benefits of omalizumab as add-on therapy in patients with severe persistent asthma who are inadequately controlled despite best available therapy (GINA 2002 step 4 treatment): INNOVATE. Allergy 2005;60:309 16.

# # #

Novartis Media Relations

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Ulrike Engels-Lange
Novartis Pharma Communications
+41 61 324 8790 (direct)
+41 79 264 4140 (mobile)
ulrike.engels-lange@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
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: October 6, 2008

By: /s/ MALCOLM B. CHEETHAM

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