NOVARTIS AG
Form 6-K
April 09, 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 8, 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 -

ACZ885, a new biological drug in development, shows potential in treating serious life-long autoinflammatory diseases

- *Patients with inherited autoinflammatory conditions achieved long-lasting remission after treatment with ACZ885*[(1),(2)]

- *Human monoclonal antibody ACZ885 blocks interleukin 1β, a key chemical messenger that causes inflammation and tissue destruction*

- *Autoinflammatory diseases produce symptoms such as fever, joint pain and skin rash and can lead to severe complications*

- *ACZ885 also being investigated for rheumatoid arthritis using innovative personalized approach to treatment*

Basel, April 8, 2008 New data demonstrate that ACZ885, a human monoclonal antibody in Phase III development, achieves long-lasting clinical remission in patients with genetic autoinflammatory diseases[(1),(2)].

The results indicate that ACZ885 could develop into a major therapeutic advance in the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), a group of rare but serious life-long diseases including Muckle Wells Syndrome[(3)].

In the Phase II study, CAPS patients treated with ACZ885 showed an improvement in symptoms within one day and all achieved complete clinical remission within seven days[(1)]. Clinical remission lasted 115 days on average[(1)]. The results were presented today at the Fifth International Congress on Familial Mediterranean Fevers and Systemic Autoinflammatory Diseases in Rome.

The latest findings are a promising step forward for patients with rare autoinflammatory diseases, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. We are optimistic that ACZ885 could become an innovative treatment option for patients affected by inflammatory diseases involving IL-1β. ACZ885 reflects our commitment to developing innovative treatments that address unmet medical needs, in patients with serious but rare conditions.

ACZ885 is also being investigated in more common inflammatory diseases such as rheumatoid arthritis (RA), which affects up to 1% of the world s population[4]. A study in RA currently under way uses an innovative tailored approach with biomarkers to predict response to treatment. If successful, this will give suitable patients a personalized approach to treating their disease.

Unlike other agents, ACZ885 blocks solely interleukin 1β (IL-1β), one form of interleukin-1 protein that causes the body to attack itself in autoinflammatory diseases such as CAPS. Patients affected by CAPS have symptoms such as fever, fatigue, skin rash, painful joints and muscles, and severe headache. They can also suffer from more severe complications like hearing loss and amyloidosis, a group of diseases in which some organs accumulate high deposits of proteins causing kidney failure and leading to dialysis or transplantation[3].

The study results presented in Rome involved 20 patients with CAPS aged between six and 50 years, who received an injection of ACZ885 every two months dosed at 150 mg for adults or two mg per kilo body-weight for children[1],[2]. ACZ885 was well-tolerated in the study, with only mild skin reactions at the injection site. The most common adverse events were upper respiratory tract infections[2].

Traditional drugs for autoinflammatory diseases, which work by suppressing the immune system as a whole, are not always effective, while newer therapies control the disease better but are short-acting, said Professor Philip Hawkins of the National Amyloidosis Centre at the Royal Free and University College Medical School, London. The data for ACZ885 are exciting for the medical community as symptoms disappeared within a few days of treatment and the response was sustained, so patients may only need to be treated every second month.

The potential of ACZ885 is reflected in its broad development program. In addition to the Phase III study program in CAPS and the Phase II study in rheumatoid arthritis, a Phase II study is also ongoing in another condition called Systemic Onset Juvenile Idiopathic Arthritis (SJIA).

Orphan drug status has already been granted to ACZ885 in the European Union and US for treating CAPS, and in the EU for SJIA. Orphan drugs are those designed to treat serious or life-threatening diseases affecting less than 200,000 people (in the US)(5) or less than five out of 10,000 people (in the EU)(6).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as in development , potential , can , being investigated , could , promising , optimistic , commitment , will , may , or similar expressions, or by express or implied discussions regardin potential marketing approvals for ACZ885 or regarding potential future revenues from ACZ885. 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 ACZ885 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that ACZ885 will be approved for sale in any market. Nor can there be any guarantee that ACZ885 will achieve any levels of revenue in the future. In particular, management s expectations regarding ACZ885 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) Lachmann H.J. et al. Treatment of cryopyrin associated periodic fever syndrome with a fully human anti-IL-beta monoclonal antibody (ACZ885): results from a subcutaneous administration study, oral presentation at FMFSAID, April 8 2008, Rome, Italy.

(2) Kuemmerle-Deschner J.B. et al, Long lasting response to ACZ885 in patients with Muckle-Wells Syndrome, oral presentation at FMFSAID, April 8 2008, Rome, Italy.

(3) http://www.capscommunity.com/index.html, Last access March 17, http://www.orpha.net/consor/cgi-bin/index.php, Last access March 17

(4) Data Monitor Report, 2007.

(5) http://www.fda.gov/orphan, Last access March 17, 2008

(6) http://ec.europa.eu/health/ph_threats/non_com/rare_6_en.htm, Last access March 17, 2008

# # #

Novartis Media Relations

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

Irina Ferluga
Novartis Pharma Communications
+ 41 61 324 24 22 (direct)
+ 41 79 824 11 21 (mobile)
irina.ferluga@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Ruth Metzler-Arnold	+41 61 324 9980		
Katharina Ambuehl	+41 61 324 5316	**North America Office**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
John Gilardi	+41 61 324 3018	Jill Pozarek	+1 212 830 2445
Jason Hannon	+41 61 324 2152	Edwin Valeriano	+1 212 830 2456
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		
Central phone no:	+41 61 324 7944		
Fax no:	+41 61 324 8444	Fax no:	+1 212 830 2405
e-mail: investor.relations@novartis.com		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: April 8, 2008

By: /s/ MALCOLM B. CHEETHAM

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