NOVARTIS AG
Form 6-K
February 28, 2007

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 February 27, 2007

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

Enclosures:

Novartis committed to making Galvus® available for patients with type 2 diabetes after US regulators issue approvable letter (Basel, February 26, 2007)

Focetria® pandemic influenza vaccine receives positive European Union regulatory agency opinion supporting approval (Basel, February 23, 2007)

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

- Investor Relations Release -

Novartis committed to making Galvus® available for patients with type 2 diabetes after US regulators issue approvable letter

Novartis confident in safety and efficacy of Galvus as a once-daily oral treatment for patients with type 2 diabetes, over 8,000 patients in clinical trial program

US Food and Drug Administration (FDA) requests additional data, including a clinical study in patients with renal impairment

Discussions to continue with the FDA to obtain final US approval for Galvus

Basel, February 26, 2007 Novartis announced today that it has received an approvable letter from the US Food and Drug Administration (FDA) for Galvus® (vildagliptin), under review for US approval as a new once-daily oral treatment for patients with type 2 diabetes.

An approvable letter means the FDA is prepared to approve an investigational medicine and contains conditions that must be met prior to final US approval. The FDA has requested additional data, including a clinical study to demonstrate the safety and efficacy of Galvus in specific patient groups with renal (kidney) impairment.

We are confident in the safety and efficacy of Galvus and will continue working closely with the FDA to agree on what final actions are required to obtain US approval, said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

The 2007 financial outlook previously communicated in January remains unchanged for the Pharmaceuticals division and for the Group.

Galvus was submitted for US approval in January 2006 as a new therapy to reduce blood sugar levels in patients with type 2 diabetes, both as a monotherapy and in use with other anti-diabetic medicines.

The global clinical trial program to date has included over 8,000 patients, with some 5,500 treated with Galvus. Submission for European Union approval was made in August 2006.

Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as committed, approvable, confident, continue, will continue, financial outlook, or similar expressions, or by express or implied discussions regarding potential future Galvus clinical trial results, potential future approvals to market Galvus, potential future sales of

Galvus, or the financial outlook of the Group and its Pharmaceuticals Division. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee as to the results of any future clinical trials regarding Galvus, that any future regulatory filings will satisfy the FDA s and other health authorities requirements regarding Galvus, that Galvus will be approved by the FDA for any indication, that Galvus will ever be brought to market in the US, the EU or any other market, or that Galvus will reach any particular level of sales. Neither can there be any guarantee that the Group, or the Pharmaceuticals Division, will achieve any particular level of financial results. In particular, management s expectations regarding the approval and commercialization of Galvus could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, or unexpected new clinical data, including unexpected results from the clinical trials required by FDA; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the ability to obtain or maintain patent or other proprietary intellectual property protection, as well as factors discussed in the Company s Form 20-F filed with the US Securities and Exchange Commission. 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, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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- Investor Relations Release -

Focetria® pandemic influenza vaccine receives positive European Union regulatory agency opinion supporting approval

Approval of Focetria, an immune enhancing pandemic influenza vaccine, would allow for more rapid response in the event of influenza pandemic

Basel, February 23, 2007 Novartis announced today that it has received a positive opinion supporting European Union regulatory approval of the human vaccine Focetria® for use in the event of an pandemic influenza outbreak, such as one that could be caused by the H_5N_1 virus.

The Committee for Medicinal Products for Human Use (CHMP), which reviews applications for all 27 countries in the European Union as well as Iceland and Norway, has recommended approval of this new vaccine. The European Commission generally follows the recommendations of the CHMP and delivers its final decision within two to three months.

The EU submission for Focetria was considered a mock-up since it lays the groundwork for a more rapid approval and availability of a specific vaccine once a pandemic has been declared.

Focetria would be manufactured to contain the pandemic influenza strain declared at the time of a pandemic along with the proprietary adjuvant MF_{59} developed by Novartis. Studies have shown that MF_{59} could boost the body s immune response to the vaccine s active constituent and extend vaccine supplies by allowing for smaller amounts of viral antigens to be used in each dose compared to vaccines without this additive.

The availability of a pandemic influenza vaccine soon after the declaration of a pandemic is essential to reduce disease burden and deaths. This positive recommendation for our proprietary MF_{59}-adjuvanted pandemic vaccine brings us one step closer to achieving public health and pandemic preparedness goals, said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics, a division of Novartis.

We are committed to working with governments and international organizations to reduce the impact of an influenza pandemic through ongoing research and development projects for pre-pandemic and pandemic influenza vaccines, Reinhardt said.

Novartis submitted the Focetria mock-up file for EU approval in early 2006. Once the World Health Organization (WHO) declares a pandemic, Novartis will submit a revised application to the European Medicines Agency (EMEA) to incorporate the identified viral strain. This revised application can be approved more quickly than a totally new application. The filing for the Novartis

mock-up vaccine was based on clinical studies involving the MF_{59} adjuvant and different H_5N_1 strains with pandemic potential.

Separately, Novartis has submitted an MF_{59}-adjuvanted H_5N_1 pre-pandemic influenza vaccine for EU approval based on the same technology as Focetria. This vaccine is intended for use prior to a pandemic declaration to help prime and boost the immune system of those receiving the vaccine to better defend against infections from a H_5N_1 virus.

Novartis commitment to pandemic preparedness

Novartis is working closely with government and regulatory officials worldwide to support pandemic preparedness efforts. Novartis has engaged in discussions with several governments concerning pandemic influenza vaccine supply and has provided H5N1 vaccines for stockpiling, notably in the US and UK.

In January 2007, the US Department of Health and Human Services awarded Novartis a USD 55 million contract to further develop the adjuvant technology of MF_{59} in the US to potentially extend vaccine supplies in case of a pandemic outbreak.

An adjuvant is a substance added to a vaccine to enhance the body s immune response to the vaccine s active constituent, called the antigen. Research supporting the use of the MF_{59} adjuvant includes:

Clinical trial data presented at the Second International Conference on Influenza Vaccines for the World (IVW 2006) confirming that the addition of the MF_{59} adjuvant can augment antibody response and increase protection of subjects against circulating influenza strains not included in the vaccines

Clinical research published in *The Lancet* in 2001 demonstrating that an MF_{59}-adjuvanted vaccine, based on the non-pathogenic H_5N_3 virus strain, induced antibodies against H_5N_1 influenza virus at lower antigen levels

A study published in the *Journal of Infectious Diseases* in 2005 showing that an MF_{59}-adjuvanted vaccine induced broadly cross-reactive antibodies capable of neutralizing H_5N_1 viruses isolated from a number of Southeast Asian countries between 1997 and 2004

Clinical trial data, supported by the US National Institutes of Health (NIH), of an MF_{59}-adjuvanted vaccine against an H_9N_2 avian influenza virus that were published in 2006 in the online edition of *Clinical Infectious Diseases;* in this study, an MF_{59}-adjuvanted vaccine induced antibody levels believed to offer protection using one quarter of the dose level used against a seasonal flu strain

Additionally, Novartis has developed a new vaccine manufacturing process that uses cell cultures rather than chicken eggs for antigen production. The new technology may reduce production time to meet demands of influenza outbreaks and to combat evolving strains of the virus, including avian influenza strains that are difficult to grow in eggs. The cell culture-based vaccine Optaflu® was submitted for EU regulatory approval in July 2006 and is currently in clinical studies in the US.

About H5N1 avian influenza

Global health authorities have identified H_5N_1 avian influenza as an aggressive viral strain with pandemic potential. While researchers have not quantified the likelihood of an outbreak, to date H_5N_1 has caused serious illness in Southeast Asia in more than 250 people. The mortality rate of patients investigated has been over 50 percent(1).

An influenza pandemic would be expected to spread quickly globally; licensing and production of sufficient quantities of pandemic vaccines is therefore an enormous challenge. The WHO recommends early vaccine development and use to reduce disease severity and mortality and stresses the need to work collaboratively with researchers and manufacturers towards ensuring that as much as possible, vaccines and antiviral drugs are available at the start of a pandemic(2).

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About Novartis

Novartis Vaccines and Diagnostics is a new division of Novartis focused on the development of preventive treatments and tools. Novartis Vaccines is the world s fifth-largest manufacturer and second-largest supplier of influenza vaccines in the US. The division s products also include meningococcal, pediatric and travel vaccines. Chiron, the blood testing and molecular diagnostics business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world s blood supply.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world.

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(2) WHO Strategic Action Plan for Pandemic Influenza 2006-2007, WHO website http://www.who.int/csr/resources/publications/influenza/WHO_CDS_EPR_GIP_2006_2c.pdf, accessed February 6, 2007

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: February 27, 2007

By: /s/ MALCOLM B. CHEETHAM

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