NOVARTIS AG
Form 6-K
June 01, 2006

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 May 31, 2006

(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: ý 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**: ý

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**: ý

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**: ý

- Investor Relations Release -

Novartis International AG
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Novartis Corporation

608 Fifth Avenue

New York, NY 10020

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Date: May 31, 2006

Sandoz gets precedent-setting US approval for Omnitrope® as first follow-on version of a previously approved recombinant biotechnology drug

- US approval a breakthrough in goal of making high-quality and cost-effective follow-on biotechnology medicines available for patients

- Omnitrope now approved for treatment of growth disorders in children and adults in the US, the European Union and Australia

- Sandoz committed to bringing other follow-on biotechnology medicines to patients worldwide following patent expiry

HOLZKIRCHEN, Germany, May 31, 2006 Sandoz announced today that the US Food and Drug Administration has granted approval for the company s recombinant human growth hormone Omnitrope® as the first follow-on version of a previously approved recombinant biotechnology drug in the US.

Omnitrope was approved in the US using the so-called 505(b)(2) pathway of the Hatch-Waxman Act, becoming the first recombinant copy of a biotech drug to be approved by this manner.

Omnitrope is indicated for treatment of growth disorders in children and adults.

The FDA s approval is a breakthrough in our goal of making high-quality and cost-effective follow-on biotechnology medicines like Omnitrope available for health care providers and patients worldwide, said Dr. Andreas Rummelt, CEO of Sandoz. The approval of Omnitrope is a major step forward in bringing needed clarity to the approval process for follow-on biotechnology medicines in the US.

The FDA s decision follows the approval of Omnitrope on April 19 by the European Commission. Omnitrope is now on the market in Germany, with launches planned for additional countries in Europe later this year. Omnitrope is also available in Australia, where it was launched in November 2005.

Sandoz believes that rigorous scientific criteria should be consistently applied to the approval process for all follow-on biotechnology medicines. However, the unnecessary or unethical duplication of animal studies and human clinical trials should be avoided so that resources are not wasted that could otherwise be invested in innovation and continuous improvement.

Sandoz also believes that these types of medicines should be approved and produced once patents have expired without specific reference to the trade secrets and confidential commercial information of innovators.

Biotechnology medicines are produced in living organisms altered by recombinant technology, and being proteins, are larger than smaller pharmaceutical molecules produced by organic synthesis. However, using advanced product development, analytical methodologies and manufacturing processes, companies like Sandoz can manufacture high quality medicines and bring them to market with savings for patients and payors.

As more recombinant biotechnology medicines lose protection in the coming years, these products are expected to play a key role in the growth strategy of Sandoz.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as committed to bringing , planned , expected , or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Omnitrope , or future approvals of other follow-on protein products (FOPPs). Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Omnitrope to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Omnitrope will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. Management's expectations regarding Omnitrope could be affected by, among other things, additional analysis of Omnitrope clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry, and general public pricing pressures; and other risks and factors referred to in the Company'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 this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. Sandoz has a portfolio of more than 600 active substances in over 5 000 forms worldwide. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal

medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these drugs along with pharmaceutical and biotechnological active substances and Anti-Infectives. In addition to the strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and EonLabs (U.S.) and sells its products in more than 110 countries. In 2005, Sandoz employed around 20,000 people worldwide and has annual sales of USD 4.7 billion.

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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: May 31, 2006

By: /s/ MALCOLM B. CHEETHAM

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