

NOVARTIS AG
Form 6-K
March 31, 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 March 12, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Edgar Filing: NOVARTIS AG - Form 6-K

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: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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: ☐ **No:** ☒

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: ☐ **No:** ☒

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

- Investor Relations Release -

Sandoz enhances patient access with launch of Omnitrope™ Pen 5 with liquid cartridge

- New delivery system enables patient convenience
- Priced 35% below the originator product, furthering patient access to Omnitrope, first follow-on version of a recombinant biotechnology drug

Princeton, New Jersey, March 12, 2008 Sandoz today announced the introduction in the United States of Omnitrope™ Pen 5 with liquid cartridge, a new form of the first follow-on version of a previously approved recombinant biotechnology drug approved by the Food and Drug Administration. Omnitrope, a somatotropin (rDNA origin) for injection recombinant, is approved for long-term treatment of pediatric patients who have growth failure and long-term replacement therapy in adults with growth hormone deficiency.

The Omnitrope Pen 5 with liquid cartridge approved by the FDA is available in 5 mg strength at a price of USD 33.65/mg, which is approximately 35% less than the published price for Genotropin®, the comparator reference product, and other leading recombinant growth hormones. This new delivery system is more convenient for patients because the liquid is already dissolved in a ready-to-use cartridge and can be loaded into the pen for injection.

According to the FDA, Omnitrope is highly similar to Genotropin in its pharmacokinetic/pharmacodynamic, safety and efficacy profiles, which is a very high regulatory standard and the same comparability standard currently applied to brand products when they make manufacturing changes.

The Omnitrope Pen 5 with liquid cartridge represents Sandoz commitment to meeting the needs of patients through providing more convenient delivery systems, said Bernhard Hampl, chief executive officer of Sandoz Inc., the US subsidiary of Sandoz. This launch is another milestone in our continuing efforts to provide US healthcare providers and patients with greater access to high-quality biologic medicines at more affordable prices.

Edgar Filing: NOVARTIS AG - Form 6-K

An Omnitrope liquid pen system has been available in Europe since spring 2007. A lyophilized powder form of Omnitrope was launched in the US by Sandoz in January 2007, following its approval by the FDA in May 2006 under the 505(b)(2) Pathway of the Hatch-Waxman Act. Shortly prior to that, Omnitrope was also the first biosimilar to be approved in Europe. No other follow-on biologic (referred to as biosimilars in Europe) has received approval and been made available to patients in both regions.

Sandoz strongly supports a balanced position on follow-on biologics, which advocates that the same standards of high quality and science consistently be applied to all medicines, ensures respect for legitimate intellectual property, and recognizes the role that generic drugs and follow-on biologics can play in the health care system.

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 950 compounds and sells its products in more than 130 countries. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances and anti-infectives. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and Eon Labs (US). In 2007, Sandoz employed around 23,000 people worldwide and posted sales of USD 7.2 billion.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "continuing efforts" or similar expressions, or by express or implied discussions regarding the launch of Omnitrope Pen 5, potential future approvals of other follow-on biologic products, or regarding potential future revenues from Omnitrope Pen 5 or from any such other follow-on biologic products. Such forward-looking statements reflect the current views of Sandoz regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the launch of Omnitrope Pen 5 will be successful. Nor can there be any guarantee that any other follow-on biologic products will be approved for sale. Neither can there be any guarantee that Omnitrope Pen 5, or any such other follow-on biologic products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; an inability to obtain needed legislative changes to create new regulatory approval pathways for follow-on biologic products; competition in general; production delays or business interruption generally; 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 U.S. 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.

For further information

Charles A. Bruns
Sandoz US Communications
+1 609 627 8881 (direct)
charles.bruns@sandoz.com

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

Omnitrope™ is a trademark of Sandoz.

Genotropin® is a registered trademark of Pfizer.

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: March 12, 2008

By: /s/ MALCOLM B. CHEETHAM

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