

NOVARTIS AG
Form 6-K
February 17, 2009

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 13, 2009

(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: ☒ Form 40-F: ☐

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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 receives European Commission approval for biosimilar filgrastim

- *Sandoz receives approval for its third biosimilar medicine, further reinforcing pioneer position in field*
- *Approval increases access to high-quality oncology medicines, offering patients comparable quality, safety and efficacy to reference product combined with greater cost-effectiveness*
- *Sandoz committed to bringing more high-quality biosimilars to patients worldwide*

Holzkirchen, February 13, 2009 Sandoz has received final approval for its third biosimilar, filgrastim, paving the way for this important oncology medicine to be made available to patients across the European Union.

Filgrastim is indicated for the treatment of neutropenia, a condition characterized by a lack of neutrophils – one of the most common types of white blood cells – whose role is to fight infection in the body. Neutropenia is often associated with chemotherapy or bone marrow transplants, as well as advanced HIV infections. Filgrastim is a natural protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells.

The Sandoz product is approved for the same range of indications as the reference product, Neupogen® (1) and offers patients comparable quality, safety and efficacy combined with greater cost-effectiveness. The novel Sandoz filgrastim needlestick protection device decreases the risks of injury and exposure to blood-borne infection, thus contributing significantly to protecting health professionals.

Sandoz CEO Jeff George says: As the pioneer of biosimilars and a company with a global reputation for offering high quality medicines at affordable prices to patients and payors worldwide, Sandoz is looking forward to providing this important new cost-effective option for oncology patients.

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Filgrastim particularly helps patients receiving chemotherapy to increase their neutrophil counts, meaning they can better avoid the risk of the serious life threatening infections that so often force clinicians to change their optimal therapeutic chemotherapy regimen, dose or schedule.

Sandoz is the only company with marketing authorization for more than one biosimilar medicine. In a precedent-setting decision in April 2006, Sandoz received the first-ever EU approval for a biosimilar medicine, human growth hormone Omnitrope®. Binocrit® / Epoetin alfa Hexal®, the first follow-on erythropoetin and the first complex (glycoprotein) biosimilar, was approved in the EU in August 2007 and

launched the same year. Sandoz has a comprehensive biopharmaceuticals pipeline, with numerous projects at various stages of development.

The European Commission approval followed a positive opinion issued in November by the European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP), which provides scientific reviews of medicines for the Commission.

(1) Neupogen® is a registered trademark of Amgen

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as committed, looking forward, pipeline, or similar expressions, or by express or implied discussions regarding potential marketing approvals for other biosimilar products, or regarding potential future revenues from filgrastim or other biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management 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 other biosimilar products will be submitted for approval or approved for sale in any market. Nor can there be any guarantee that filgrastim, or other biosimilar products, will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected developmental delays, including unexpected clinical or other laboratory data; unexpected regulatory actions or delays or government regulation generally; 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.

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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 approximately 1000 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 2008, Sandoz employed around 23,000 people worldwide and posted sales of USD 7.6 billion.

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For further information

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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: February 13, 2009

By: /s/ MALCOLM B. CHEETHAM

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