NOVARTIS AG
Form 6-K
June 30, 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 June 25, 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: 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 -

Sandoz receives approval for first-ever Japanese biosimilar

- *Sandoz receives approval for first-ever Japanese biosimilar, recombinant human growth hormone somatropin, further reinforcing global pioneer position in field*
- *Approval paves way for greater access to high-quality biopharmaceuticals in Japan, the world s second largest pharmaceutical market*
- *Sandoz somatropin already marketed as Omnitrope® in EU, US and Australia*

Holzkirchen, June 25, 2009 Sandoz has received marketing authorization for the first-ever Japanese biosimilar, recombinant human growth hormone somatropin. The precedent-setting decision further reinforces Sandoz s global leadership position in the rapidly-emerging market for biosimilars, or follow-on versions of existing state-of-the-art biopharmaceuticals.

Sandoz CEO Jeff George said: We are pleased that Sandoz, the pioneer in biosimilars and a company with a global reputation for offering high quality medicines at affordable prices, is paving the way in Japan as well. Together with our parent company Novartis, we are fully committed to broadening access to innovative and affordable biopharmaceuticals over the years and decades to come, both in Japan and worldwide.

The Ministry of Health, Labor and Wealth (MHLW) announced the approval on June 22, barely three months after the Japanese authorities published guidelines that paved the way for a national biosimilar regulatory pathway, based on similar scientific principles to the approval pathway already in place in the European Union.

The Sandoz product will be marketed in Japan as Somatropin BS S.C. injection 5mg / 10mg [Sandoz]. It is approved for the treatment of growth hormone deficiency in children and growth disturbance associated with Turner s syndrome or chronic renal insufficiency. This is the same range of indications covered by the reference product, Genotropin®, as approved in Japan(1). It is approved on the basis that it offers patients comparable quality, safety and efficacy to the reference product.

Sandoz pioneered the field of biosimilars / follow-on biologics with the approval and subsequent launch of Omnitrope® in the US and Europe. Omnitrope was the first such product to be made available to patients in both regions and the first ever medicine to be approved in the EU as a biosimilar, the European regulatory term for such products. Sandoz today is the only company with three biosimilar medicines marketed in Europe.

Biosimilars are an integral part of the Sandoz strategy to focus on difficult-to-make products that provide added patient benefits. Due to the rising costs of health care and the growing need for more complex treatments, they will play an increasingly important role in ensuring and broadening global access to medicines. Sandoz is building a strong global biosimilar pipeline, with numerous projects at all stages of development.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as paves way for, paving the way, committed, will, or similar expressions, or by express or implied discussions regarding potential marketing approvals for other biosimilar products, or regarding potential future revenues from somatropin/Omnitrope 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 somatropin/Omnitrope, 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.

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.

# # #

(1) Genotropin® is a registered trademark of Pfizer

For further information

Eric Althoff
Novartis Global Media Relations
+41 61 32 47999
eric.althoff@novartis.com

Chris Lewis
Sandoz Global Communications
+49 172 141 8749
chris.lewis@sandoz.com

Novartis Investor Relations

International:
Ruth Metzler-Arnold
Pierre-Michel Bringer
John Gilardi
Thomas Hungerbuehler
Isabella Zinck
Central phone no: +41 61 324 7944
E-mail: investor.relations@novartis.com

North America:
Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456
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: June 25, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting