NOVARTIS AG
Form 6-K
September 06, 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 September 5, 2007

(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**

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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 -

Cubicin® receives European approval to expand use to treating two additional types of life-threatening hospital infections

- *Cubicin approved for treating two more life-threatening Staphylococcus aureus infections: right-sided infective endocarditis (RIE) and certain bacteremias*

- *Cubicin clinically proven to target both Staphylococcus aureus and methicillin-resistant Staphylococcus aureus (MRSA) with equal efficacy(1)*

- *These serious infections can cause death in up to one-third of patients if not treated quickly and effectively(2)*

Basel, September 5, 2007 Cubicin® (daptomycin) has received European Commission approval for expanded use in helping patients suffering from two types of life-threatening bacterial infections that commonly occur during hospital stays, including infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) strains.

The two new indications approved for Cubicin were right-sided infective endocarditis (RIE) due to *Staphylococcus aureus (S. aureus)*, an infection of the heart valve, and *S. aureus* bacteremia (SAB), a bloodstream infection, in cases when associated with RIE or with complicated skin and soft-tissue infections (cSSTI).

Cubicin first received European approval in January 2006 for use in treating cSSTI infections caused by Gram-positive bacteria.

In the UK alone, more than 15,000 patients are estimated to contract SAB infections every year(3). If not quickly and effectively treated, up to one-third of these patients may die from the infections(2). With growing resistance to current treatments, these types of infections are becoming an increasingly serious public health challenge(2).

The use of Cubicin in treating patients with bacteremia and endocarditis caused by *S. aureus* has been supported by landmark trial data published in *The New England Journal of Medicine*.

A head-to-head study demonstrated that Cubicin was equally effective against both methicillin-susceptible and methicillin-resistant *S. aureus* bloodstream infections(1). Results also showed Cubicin successfully treated patients with SAB or RIE infections with the same efficacy as the current standards of care, which is vancomycin or semi-synthetic penicillin combined with initial gentamicin therapy. Additionally, impaired kidney function, a common side-effect of antibiotics used to treat these infections, was significantly lower in patients receiving Cubicin than in those treated with the comparator drugs(1).

With the growing rates of MRSA infections, the need to treat patients quickly even before the infecting organism can be confirmed is strong. Daptomycin can be used empirically to cure both methicillin-susceptible *Staphylococcus aureus* and MRSA infections, said Dr. Christoph Naber, Assistant Medical Director of the Department of Cardiology at the University of Duisburg-Essen and founding member of the German League for Infectious Diseases. Daptomycin was proven to treat both infections with equal efficacy and overall favorable safety and tolerability.

As the first in a new class of antibiotics called cyclic lipopeptides, Cubicin rapidly resolves serious Gram-positive hospital infections with a unique mode of action, killing bacteria rather than limiting growth, resulting in negligible bacterial cell lysis(4). This means that dead bacteria are left intact, preventing them from releasing their toxic contents into the bloodstream.

While the current standard of treatment often requires combination therapies, Cubicin is a simpler approach to Gram-positive infections as a once-daily monotherapy that requires no routine therapeutic drug monitoring.

Expanding the use of Cubicin for additional life-threatening infections signals our commitment to the challenges of increasing resistance to many antibacterials in the hospital setting, said James Shannon MD, Global Head of Development at Novartis Pharma AG.

Cubicin offers physicians an effective and well-tolerated therapeutic option that can be used quickly and easily to help patients begin recovery rapidly.

Cubicin was developed by, and is a registered trademark of, Cubist Pharmaceuticals, Inc., which markets the product in the US for the treatment of complicated skin and skin structure infections and *S. aureus* bacteremia, including right-sided endocarditis. Novartis has the exclusive rights to commercialize Cubicin across Europe, Australia, New Zealand, India, and certain countries in Central America, South America and the Middle East.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, may, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Cubicin or regarding potential future revenues from Cubicin. Such forward-looking statements reflect the current views of the Novartis group of companies regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Cubicin to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Cubicin will be approved for any additional indications or labelling in the EU or any other market, nor can there be any guarantee that Cubicin will achieve any particular sales levels. In particular, management s expectations regarding Cubicin could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG s 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 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 more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Fowler VG, Jr., Boucher HW, Corey GR, et al. Daptomycin versus standard therapy for bacteremia and endocarditis caused by Staphylococcus aureus. The New England journal of medicine 2006;355(7):653-65.

(2) Cosgrove SE, Sakoulas G, Perencevich EN, Schwaber MJ, Karchmer AW, Carmeli Y. Comparison of mortality associated with methicillin-resistant and methicillin-susceptible Staphylococcus aureus bacteremia: a meta-analysis. Clin Infect Dis 2003;36(1):53-9.

(3) Health Protection Agency. Bacteremia - Staphylococcus aureus bacteremia: voluntary reporting in England, Wales and Northern Ireland: January to December 2005. CDR Weekly 2006:16(33): 4.

(4) Ginsburg I. The role of bacteriolysis in the pathophysiology of inflammation, infection and post-infectious sequelae. Apmis 2002;110(11):753-70.

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Novartis Media Relations

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 1408 (mobile)
john.gilardi@novartis.com

Birgit Gronkowski
Novartis Pharma Communications
+41 61 324 8790 (direct)
+41 79 820 1719 (mobile)
birgit.gronkowski@novartis.com

e-mail: media.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: September 5, 2007

By: /s/ Malcolm B. Cheetham

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