NOVARTIS AG
Form 6-K
October 23, 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 October 22, 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

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

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- Investor Relations Release -

Voltaren® Gel receives US regulatory approval as the first approved topical prescription treatment for pain associated with osteoarthritis

First US approval for a prescription NSAID (non-steroidal anti-inflammatory drug) treatment that can be applied directly to site of osteoarthritis pain

Voltaren Gel the only prescription topical medication proven to significantly reduce osteoarthritis pain in both the knees and the joints of the hands

Offers highly effective pain relief with minimal drug absorption throughout the body shown to be 94% less than comparable oral diclofenac treatment

Basel, October 22, 2007 Voltaren® Gel (diclofenac sodium topical gel) 1% has received US regulatory approval as the first topical prescription treatment that patients can apply directly to sites of pain associated with osteoarthritis.

The US Food and Drug Administration (FDA) granted the approval for Voltaren Gel, which is a non-steroidal anti-inflammatory (NSAID) medication, for use in treating pain associated with osteoarthritis in joints amenable to topical treatment, such as the knees and those of the hands.

Osteoarthritis is a chronic condition characterized by the breakdown of cartilage in the joint.

Clinical trials have demonstrated Voltaren Gel to be highly effective in treating osteoarthritis pain in the hands and knees, which are the body s most commonly affected joints. It is the first topical osteoarthritis treatment to have proven its effectiveness in both the hands and knees through clinical trials.

Voltaren Gel, which will be marketed in the US by the OTC business unit since this is the case in many other countries, delivers effective pain relief with a favorable safety profile as its systemic absorption is 94% less than the comparable oral diclofenac treatment.

Voltaren Gel is proven to be effective for osteoarthritis of the hand and knee and has a favorable safety profile. The combination of benefit and safety provides a welcome new treatment approach for osteoarthritis, offering patients an alternative to oral therapies, said Roy Altman, MD, Professor of Medicine in the Division of Rheumatology and Immunology at UCLA in Los Angeles and Past President of the Osteoarthritis Research Society International. Voltaren Gel delivers the proven efficacy of diclofenac with significantly less systemic absorption, minimizing the risk of side effects.

The efficacy and safety of Voltaren Gel were studied in more than 900 patients with knee or hand osteoarthritis. The US approval was based on several studies, including the results of two randomized, double-blind, placebo-controlled efficacy studies and a 12-month safety study.

Voltaren Gel was shown to significantly reduce pain in hand and knee osteoarthritis, with pain relief sustained through the end of treatment. After six weeks of treatment in an efficacy study of patients with osteoarthritis of the hand, results showed that pain levels were reduced by nearly half (46%). In a 12-week study in patients with osteoarthritis of the knee, Voltaren Gel showed a 51% reduction in pain.

Voltaren Gel represents an important clinical milestone it is the first prescription topical treatment in the US shown to relieve osteoarthritis pain and to clinically prove efficacy in treating both the knees and hands, said Jorge Insuasty, MD, Senior Vice President, Research and Development in the Group s OTC business unit. Patients now have the option to effectively treat osteoarthritis pain at the source with favorable tolerability.

Approximately 21 million people in the US have osteoarthritis,(1) and the aging population in the US means 72 million more will be at risk for developing the condition by 2030.(2) Osteoarthritis is a chronic, painful condition that often leads to working limitations and reduced overall health.(3)

About osteoarthritis

Osteoarthritis is a chronic condition characterized by the breakdown of cartilage in the joint. Cartilage cushions the ends of the bones in joints such as knees, hands, elbows, wrists, ankles and feet which allows for easy movement. When cartilage erodes, bones can rub together, resulting in pain and loss of free movement in the joint.(3) The most common symptoms include pain, joint soreness, stiffness and deterioration of overall coordination, posture and walking.

Arthritis and related conditions, such as osteoarthritis, cost the US economy nearly USD 128 billion per year in medical care and indirect expenses, including lost wages and production.(4)

Despite the high prevalence of osteoarthritis, there is no cure for this disease, which tends to progressively reduce mobility and the overall health state in the affected patients.

About Voltaren Gel

Voltaren Gel provides 1% diclofenac sodium in a topical gel formulation. It is a non-steroidal anti-inflammatory (NSAID) medication indicated for the pain of osteoarthritis in joints amenable to topical treatment, such as the knees and those of the hands. Voltaren Gel delivers highly effective pain relief with a favorable safety profile as its systemic absorption is 94% less than comparable oral diclofenac treatment.

Important safety information

The most common adverse reactions reported in Voltaren Gel clinical trials were application site reactions in 7% of treated patients. With all NSAIDs there may be an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. The use of Voltaren Gel is contraindicated in patients with a known hypersensitivity to diclofenac. Voltaren Gel should not be administered to patients who have experienced asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Voltaren Gel is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Voltaren Gel should not be used in combination with other oral NSAIDs or aspirin because of the potential for increased adverse effects. Similarly, combined use of Voltaren Gel with other topical products, such as sunscreens and cosmetics, on the same skin area has not been tested and should be avoided because of the potential to alter local tolerability and absorption.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, often leads to, may be, can be, or similar expressions, or by express or implied discussions regarding potential future revenues from Voltaren Gel. Such forward-looking statements reflect the current views of the Company 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 Voltaren Gel will achieve any particular levels of revenue in the future. In particular, management s expectations regarding commercialization of Voltaren Gel could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data, competition in general, increased government, industry and general public pricing pressures, unexpected regulatory actions or delays or government regulation generally, 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.

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 approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit our website at http://www.novartis.com.

References

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(2) National Institute of Arthritis Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health, U.S. Department of Health and Human Services. Handout on Health: Osteoarthritis. Available at: http://www.niams.nih.gov/health_info/Osteoarthritis/default.asp. Accessed on October 17, 2007.

(3) Arthritis Foundation. Available at: www.arthritis.org. Accessed on October 17, 2007.

(4) U.S. Centers for Disease Control and Prevention (CDC). [CDC (2007) Update: National and State Medical Expenditures and Lost Earnings Attributable to Arthritis and Other Rheumatic Conditions United States, 2003. MMWR Morb Mortal Wkly Rep, 56(01):4-7].

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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: October 22, 2007

By: /s/ MALCOLM B. CHEETHAM

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