

NOVARTIS AG
Form 6-K
July 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 July 20, 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: ☒ **Form 40-F:** ☐

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Yes: ☐ **No:** ☒

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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

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- Investor Relations Release -

Aclasta® recommended for European approval as the first once-yearly treatment for women with postmenopausal osteoporosis

- *Single-dose therapy given once a year shown to provide significant bone protection benefits and may improve long-term treatment compliance⁽¹⁾*
- *Aclasta shown to reduce spine fractures by 70% and hip fractures by 40% compared to placebo in study published in New England Journal of Medicine⁽¹⁾*
- *One out of two women over 50 predicted to have an osteoporosis-related fracture in their lifetime, leading to high number of deaths, disabilities and healthcare costs⁽²⁾*
- *US regulatory submission under brand name Reclast® completed in late 2006*

Basel, July 19, 2007 Aclasta® (zoledronic acid 5 mg) has passed a major milestone after receiving a positive recommendation supporting European Union approval as the first once-yearly bisphosphonate treatment for the bone disorder postmenopausal osteoporosis.

The positive opinion from the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission, is an important step forward for women with osteoporosis. A single once-yearly 15-minute infusion of Aclasta enables patients to receive a full year of medication in one setting.

This announcement comes on the same day that the CHMP recommended approval for two other Novartis medicines, Galvus® (vildagliptin) for type 2 diabetes and Exelon® (rivastigmine transdermal patch) for Alzheimer's disease. So far this year Novartis has received a total of seven product approvals and four positive opinions from the US and European regulatory authorities, providing innovative treatments to patients and creating a strong new growth platform.

The European Commission generally follows the recommendations of the CHMP and is expected to issue a decision on Aclasta within three months. The decision will apply in all 27 EU member states plus Iceland and Norway.

Current oral therapies for osteoporosis have to be taken daily, weekly or monthly, and patients often find it difficult to follow these treatment regimens. As a result more than 50% of patients are non-compliant with therapy after a year^{(3),(4)}, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Aclasta eliminates concerns about compliance for a full year and provides excellent efficacy in protecting women against the risk of life-threatening fractures throughout that period.

Osteoporosis (literally porous bones) is the most common metabolic bone disease and causes the bones to become more and more fragile, leading to an increased risk of fracture, particularly of the spine, wrist, hip, pelvis and upper arm.

An estimated one out of two women over age 50 will suffer a broken bone as a result of osteoporosis in their lifetime, resulting in a significant increase in deaths, disabilities, injuries and healthcare costs, according to the US National Institutes of Health(2).

The CHMP recommendation was based on an extensive review of data from clinical studies in osteoporosis. The dossier includes data from the 7,700-woman Pivotal Fracture Trial, published recently in *The New England Journal of Medicine*. This demonstrated a 70% reduction in spine fractures in women using Aclasta compared to those on placebo, while the risk of hip fractures which are associated with significant mortality in older people was reduced by 41% compared with placebo(1).

This is the first time that one treatment has been shown in a single study to provide protection against all types of osteoporotic fractures across all major sites spine, hip and other non-spinal fractures.

Osteoporosis is a long-term disease that can be devastating for the 150 million people who suffer from the condition worldwide(5), and for their families and caregivers, said Steven Boonen, Professor of Medicine at the Centre for Metabolic Bone Diseases & Division of Geriatric Medicine, Leuven University, Belgium. Fractures are a significant cause of hospitalization and mortality, so an effective once-yearly medicine like Aclasta that ensures bone protection for a full year should help patients improve their quality of life as well as helping healthcare systems to better manage costs.

Aclasta was submitted to US Food and Drug Administration in late 2006 for approval in the treatment of postmenopausal osteoporosis, under the brand name Reclast®. Aclasta is already approved in more than 50 countries, including the EU, US and Canada, for use in patients with Paget's disease, a chronic disorder that causes abnormal bone growth.

Aclasta was found to be generally safe and well tolerated in clinical trials. In the Pivotal Fracture trial an increased number of cases of serious atrial fibrillation were observed in women given Aclasta compared to those on placebo (1.3% vs. 0.5% respectively)(1). However, this finding has not been observed in other clinical studies or in post-marketing experience with over 1.5 million patients treated with zoledronic acid for oncology indications. No spontaneous reports of osteonecrosis of the jaw (ONJ) a rare occurrence in the osteoporosis population treated with bisphosphonates were seen in the Pivotal Fracture Trial.

In the second half of 2007, data from a large trial in men and women with osteoporosis following hip fracture will provide additional efficacy and safety data for Aclasta.

Aclasta belongs to a class of drugs called bisphosphonates, considered the standard of care for patients with osteoporosis and Paget's disease. Aclasta works by attaching to bone, stopping excessive breakdown and rebalancing the body's natural bone remodelling process.

Zoledronic acid, the active ingredient of Aclasta, is also available under the brand name Zometa® for use in oncology indications.

Disclaimer

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as supporting European Union approval, generally follows,

expected, will, should, similar expressions or express or implied discussions regarding potential future regulatory submissions or approvals with respect to, or future sales of, of Aclasta, Reclast or Zometa. Such forward-looking statements reflect the current views of Novartis 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 Aclasta or Reclast will be approved for any additional indications in the EU, US or any additional markets or that Aclasta, Reclast or Zometa will reach any particular level of sales. In particular, management's expectations regarding Aclasta, Reclast and Zometa could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; competition in general; government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; as well as the additional factors discussed in Novartis AG's Form 20-F filed 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document 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

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- (2) National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center. Osteoporosis Overview. Department of Health and Human Services. Available at <http://www.niams.nih.gov/bone/hi/overview.htm>
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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: July 20, 2007

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial
Reporting and Accounting