

NOVARTIS AG  
Form 6-K  
April 18, 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 April 17, 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:

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 -

**Reclast® receives US approval as a highly effective treatment for patients with Paget's disease of the bone**

- *Reclast (Aclasta® in some countries) is the first new treatment in nearly a decade for Paget's disease of the bone, which affects about one million people in the US(1)*
- *Clinical data show Reclast is more effective and longer lasting than the current standard of treatment*
- *Aclasta/Reclast currently under review for EU and US approval as a once-yearly treatment for women with postmenopausal osteoporosis*

**Basel, April 17, 2007** Reclast® (zoledronic acid) has received US regulatory approval as the first new treatment in nearly a decade for patients with a bone condition known as Paget's disease, estimated to affect about one million people in the US alone(1).

Reclast, which is marketed as Aclasta® in other countries, is the first approved treatment for Paget's disease patients to be given as a single-dose infusion compared to current oral therapies that must to be taken daily for up to six months. This medicine was first launched in Germany in May 2005 for Paget's disease and is now approved in more than 50 countries.

Paget's disease is a chronic, long-lasting and often painful bone disorder that causes abnormal bone growth due to a malfunction in the body's regular bone-building process(2). An outcome can be weak and brittle bones, causing them to break more easily. Approximately four million people worldwide have the condition(3).

The fact that Reclast is both highly effective and can last for several years in most patients could make this the new standard of care for Paget's patients, said Frederick R. Singer, MD, Director of the Endocrine/Bone Disease Program at John Wayne Cancer Institute in Santa Monica, California. Current bisphosphonate therapy, while generally effective, does not induce similar long-term remissions.

Clinical studies show Aclasta/Reclast is more effective(4), starts working faster(5) and offers a longer period of remission than Actonel® (risedronate sodium)\*, the current treatment standard for patients with Paget's disease. Aclasta/Reclast is administered as a single 5 mg, 15-minute intravenous infusion by a healthcare professional.

---

\* Trademark of P&G Pharmaceuticals, Inc

We believe Aclasta/Reclast provides a critical new treatment option for people who suffer from Paget's disease, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Furthermore, we are exploring the full clinical potential of this agent in treating other metabolic bone diseases, including postmenopausal osteoporosis.

The approval by the US Food and Drug Administration (FDA) was based on efficacy and safety data comparing a single dose of Aclasta/Reclast with Actonel (30 mg risedronate) taken daily for 60 days in two identically designed six month trials. Results combined from both trials showed 96 percent of patients taking Aclasta/Reclast responded to treatment compared to 74 percent of patients taking Actonel at six months. Results of these head-to-head studies were published in the September 1, 2005 issue of the *New England Journal of Medicine*(6).

These studies also demonstrated that Aclasta/Reclast starts working faster, showing a significant difference as early as two months. Patients who took Aclasta/Reclast responded to treatment after an average of 64 days versus 89 days for those taking Actonel. Overall, the number of patients with adverse events was similar in the Aclasta/Reclast and Actonel groups.

#### **About Paget's disease**

In Paget's disease, the normal cycle of new bone replacing broken-down bone is disrupted: too much bone breaks down and the replacement bone is structurally weak. Patients may experience bone pain, skeletal deformity, pathological fractures, secondary arthritis, neurological complications and deafness that can impede their ability to perform routine activities such as walking and prolonged standing(7). Paget's disease can be difficult to diagnose and may often be left untreated as not all patients experience noticeable symptoms(7).

Paget's disease is a serious and commonly overlooked condition that can be very debilitating for some patients, said Charlene Waldman, executive director, The Paget Foundation. This approval is an important milestone for people with Paget's disease because it has been more than nine years since a new treatment option has been made available.

#### **About Aclasta/Reclast**

**HORIZON, the ongoing clinical program of Aclasta/Reclast, is one of the most comprehensive drug evaluation programs ever undertaken in the area of metabolic bone diseases. Approximately 13,000 patients worldwide have participated in the program in more than 400 centers. It is the first program to study a once-yearly dosing regimen for the prevention and treatment of postmenopausal osteoporosis. Other studies involved in the program include prevention of fractures following a hip fracture in men and women, and treatment of corticosteroid-induced osteoporosis and male osteoporosis.**

The European Medicines Agency (EMA) and FDA are currently reviewing submissions for the approval of Aclasta/Reclast as a once-yearly treatment for postmenopausal osteoporosis. Zoledronic acid, the active ingredient of Aclasta/Reclast, is also available under the brand name Zometa® for use in other indications.

The US regulatory approval of Reclast in treating patients with Paget's disease comes after Novartis supplied responses to approvable letters, which are issued when the FDA is prepared to approve an investigational medicine and contain conditions that must be met prior to final US approval.

## Disclaimer

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as estimated, could, potential, can, may, or by express or implied discussions regarding potential future regulatory approvals of Reclast/Aclasta for additional indications, or potential future sales of Reclast/Aclasta. Such forward-looking statements 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 Reclast/Aclasta will be approved for any additional indications in any market, or that Reclast/Aclasta reach any particular level of sales. In particular, management's expectations regarding Reclast/Aclasta could be affected by, among other things, unexpected regulatory actions or delays in 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 approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

---

## References

1. U.S. Department of Health and Human Services. Bone Health and Osteoporosis: A Report of the Surgeon General. 2004:68
2. Ankrom MA, Shapiro JR. Paget's disease of bone (osteitis deformans). J Am Geriatr Soc 1998;46:1025-33.
3. Mattson Jack (EPI database).
4. Lyles K, Hosking D, Miller P et al. Zoledronic Acid Produces Greater and Faster Efficacy Versus Risedronate in Patients with Paget's Disease. Osteoporos Int 2005; 16(3); S1-S15.
5. Miller P, Brown J, Hosking D et al. Zoledronic Acid Produces Higher and More Rapid Therapeutic Response Rates versus Risedronate in Patients with Paget's Disease. HORIZON TOP Trial Results. Data on file.
6. Reid IR, Miller P, Lyles K et al. A single infusion of zoledronic acid improves remission rates in Paget's disease: a randomized controlled comparison with risedronate. N Engl J Med 2005; 353: 898-908.
7. Hosking D, Meunier P, Ringe J et al. Paget's disease of bone: diagnosis and management. BMJ 1996;312:491-494.

###



**Novartis Media Relations**

**Corinne Hoff**

Novartis Global Media Relations

+41 61 324 9577 (direct)

+41 79 248 5717(mobile)

corinne.hoff@novartis.com

**Irina Ferluga**

Novartis Pharma Communications

+ 41 61 324 2422 (direct)

+ 41 79 824 1121 (mobile)

irina.ferluga@novartis.com

e-mail: media.relations@novartis.com

**Novartis Investor Relations**

**International:**

**Ruth Metzler-Arnold**

+41 61 324 7944

Katharina Ambühl

+41 61 324 5316

Nafida Bendali

+41 61 324 3514

Jason Hannon

+41 61 324 2152

Thomas Hungerbuehler

+41 61 324 8425

Richard Jarvis

+41 61 324 4353

**North America:**

**Ronen Tamir**

+1 212 830 2433

Arun Nadiga

+1 212 830 2444

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: April 17, 2007

By: /s/ Malcolm B. Cheetham

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

---