

NOVARTIS AG
Form 6-K
June 02, 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 1, 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:

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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:** ☒

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- Investor Relations Release -

FDA approves Reclast® to prevent osteoporosis in postmenopausal women with convenient less frequent dosing

- *Single infusion of Reclast increases bone mass for two years in postmenopausal women with osteopenia, a condition that can lead to osteoporosis(1)*
- *Approximately 22 million women in US have osteopenia, or low bone mass, putting them at increased risk of fractures of hip, spine and wrist(2),(3)*
- *Reclast already approved as once-yearly infusion in US and EU (under trade-name Aclasta), for the treatment of postmenopausal osteoporosis(1),(4)*

Basel, June 1, 2009 Reclast® (zoledronic acid 5 mg) Injection(1) has been approved by the US Food and Drug Administration (FDA) as the first and only therapy to prevent postmenopausal osteoporosis for two years with a single dose(1). Reclast, or Aclasta® as it is known outside the US, is already approved in more than 80 countries including the US and EU as a once-yearly infusion for the treatment of postmenopausal osteoporosis(1),(4).

The FDA decision is based on a study involving more than 500 postmenopausal women with osteopenia, or low bone mass, showing that a single infusion of Reclast significantly increased bone mineral density (BMD) at two years compared to placebo(1).

Approximately 22 million women in the US have osteopenia, putting them at increased risk of osteoporosis, a disease that causes bones to break more easily(2),(3). Osteoporosis is a major public health threat affecting an estimated 10 million men and women in the US(2).

Although low bone mass is less severe in people with osteopenia than those with osteoporosis, they are still at increased risk of fractures(5). In fact, research shows that approximately half of women who experience a fragility fracture, or a broken bone due to a fall from standing height or less, have osteopenia(6),(7),(8),(9), highlighting the importance of treating and preventing further bone loss.

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It is very important to treat postmenopausal women with low bone mass to prevent them from progressing to osteoporosis, said Mone Zaidi, MD, PhD, Professor of Medicine, Geriatrics, and Physiology and Director of The Mount Sinai Bone Program at Mount Sinai School of Medicine in New York, USA. The dosing of Reclast for the prevention of postmenopausal osteoporosis offers an advance over existing therapies since it can be given once every two years, instead of daily, weekly or monthly.

(1) The tradename is Reclast® in the US and Aclasta® in the rest of the world.

Reclast is already approved in the US as a once-yearly infusion to treat postmenopausal osteoporosis, to increase bone mass in men with osteoporosis, and to treat and prevent osteoporosis caused by glucocorticoids, commonly known as steroids. In the EU, Aclasta is approved for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture, including those with a low trauma hip fracture(4). Additionally, the Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending Aclasta for the treatment of glucocorticoid-induced osteoporosis in the EU. Aclasta/Reclast is also approved in the US and EU for the treatment of Paget's disease of bone, the second most common metabolic bone disorder, in men and women(1),(5).

We are very pleased with this latest US approval that recognizes the large body of safety and efficacy data for Aclasta/Reclast and underlines its potential to protect patients with a number of bone disorders," said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG.

Women with low bone mass in the US now have an important new option that is proven to strengthen their bones, and therefore prevent the onset of osteoporosis, for a full two years with only one infusion.

The new US indication to prevent bone loss in postmenopausal women with osteopenia was based on a two-year randomized, multi-center, double-blind, placebo-controlled study of 581 postmenopausal women older than 45 years of age. The primary endpoint was the change in BMD at two years relative to baseline(1).

This study included women in early menopause (i.e. within five years of menopause) and late menopause (i.e. more than five years from menopause)(1). Patients were divided into three groups and received either Reclast at the beginning of the study and again at one year, Reclast at the beginning of the study and placebo at one year, or placebo at the beginning of the study and placebo again at one year(1).

Reclast significantly increased lumbar spine BMD relative to placebo at the end of the two-year study(1). Treatment with Reclast given as a single dose at the beginning of the study increased lumbar spine BMD by 6.3% in the early menopause group and by 5.4% in the late menopause group at two years (both $p < 0.0001$)(1).

Aclasta/Reclast is generally safe and well tolerated. The most common adverse events associated with Aclasta/Reclast are transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occur within the first three days following Aclasta/Reclast administration and resolve within three days. The incidence of such post-dose symptoms can be reduced with the administration of paracetamol or ibuprofen shortly after Aclasta/Reclast infusion(1).

Aclasta/Reclast has been used in nearly 500,000 patients worldwide, including more than 238,000 in the US, to help prevent fractures(10). It is available in all 50 US states and reimbursed by all Medicare Part B carriers and virtually all health insurance plans(11). Reclast can be administered in physicians' offices or at one of the more than 5,600 infusion centers located throughout the US(12).

Zoledronic acid, the active ingredient in Aclasta/Reclast, is also available under the trade-name Zometa® for use in oncology indications.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "risk," "recommending," "potential," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Aclasta/Reclast or regarding

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potential future revenues from Aclasta/Reclast. 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 with Aclasta/Reclast to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aclasta/Reclast will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Aclasta/Reclast will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Aclasta/Reclast 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; 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 Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

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- (10) Novartis Internal (NPMR), based on Aclasta/Reclast vials sold in the US since launch till Feb 2009.
- (11) Novartis Health Policy; USMM; Lash Group.
- (12) Aclasta/ Reclast Ready Report; 2009, Novartis Data on File. Novartis Pharmaceutical Corporation.

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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: June 1, 2009

By: /s/ MALCOLM B. CHEETHAM

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