NOVARTIS AG
Form 6-K
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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 for the month of November 2004
(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: ý 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:** ý

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):

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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:** ý

Enclosures:

1. Following EMEA decision to review safety of COX-2 class, Novartis temporarily withdraws EU Mutual Recognition Procedure application for Prexige® (Basel, November 30, 2004)

2.

Study explores whether long-term treatment of eczema with Elidel® could reduce risk of asthma by halting "atopic march" (Florence, November 18, 2004)

3. Novartis honors scientists for outstanding contributions to research and development (Basel, November 15, 2004)

4. Femara® gains U.S. FDA approval as only post-tamoxifen treatment for early breast cancer (Basel, Switzerland, October 29, 2004)

Investor Relations

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Investor Relations Release

Following EMEA decision to review safety of COX-2 class, Novartis temporarily withdraws EU Mutual Recognition Procedure application for Prexige®

New Prexige data further strengthening product profile to be presented at Osteoarthritis Research Society International (OARSI) meeting in Chicago

Basel, November 30, 2004 Novartis Pharma AG announced today that it has withdrawn the application for the EU Mutual Recognition Procedure for Prexige® (lumiracoxib) to await the outcome of the European Medicines Agency (EMEA) review of all selective COX-2 inhibitors, which is expected to be completed in 2005. Novartis remains committed to Prexige and is continuing to work closely with regulatory authorities. The company plans to further document the safety and efficacy profile of Prexige in its regulatory dossiers by incorporating additional data.

"Novartis remains confident that Prexige offers physicians and patients a new safe and effective treatment option to relieve the symptoms of osteoarthritis and acute pain," said Dr. Jörg Reinhardt, Head of Development, Novartis Pharma AG.

New data from two clinical trials demonstrating the efficacy and tolerability of Prexige at 100 mg daily will be presented during the Osteoarthritis Research Society International (OARSI) meeting in Chicago from December 2-5, 2004. Both trials were conducted in patients with osteoarthritis (OA) and evaluated the pain intensity reduction and improvement in the functional status of patients.

Results from the landmark TARGET (Therapeutic Arthritis Research & Gastrointestinal Event Trial of lumiracoxib), which were published in August 2004 in The Lancet, demonstrated a significant 79% reduction in the incidence of upper gastrointestinal (GI) ulcer complications without compromising cardiovascular (CV) safety. The trial demonstrated that Prexige has a cardiovascular profile similar to conventional non-steroidal anti-inflammatory drugs (NSAIDs). Results also showed there was no significant difference in serious hepatic events between Prexige and the NSAID groups. TARGET was the largest GI safety outcomes study performed to date with 18,325 patients that compared Prexige against the NSAIDs ibuprofen and naproxen.

Novartis has filed applications for regulatory approval throughout the world based on data from more than 40 pre-clinical and clinical studies in osteoarthritis, rheumatoid arthritis, acute pain and primary dysmenorrhea involving more than 31,000 adult patients around the world. In addition to the United Kingdom, Prexige has been approved in 21 countries to date, including Australia, New Zealand and several countries in Latin America, including Argentina, Brazil and Mexico.

The foregoing press release contains forward-looking statements that can be identified by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Prexige (lumiracoxib). 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 any future regulatory filings will satisfy the requirements of any health authorities regarding Prexige, that Prexige will be approved under the EU Mutual Recognition Procedure or by the FDA or other country's health authorities for any indication, or that Prexige will reach any particular level of sales. In particular, management's expectations regarding Prexige could be affected by, among other things, uncertainties relating to clinical trials and product development, including any additional clinical trials which must be conducted in the future in order to satisfy the requirements or regulatory authorities; regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry, and general public pricing pressures; and competition in general; as well as factors discussed in the Company'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

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Study explores whether long-term treatment of eczema with Elidel® could reduce risk of asthma by halting "atopic march"

Pioneering research program investigates benefits of long-term disease control

Florence, November 18, 2004 A groundbreaking study now under way will establish whether effective treatment of atopic eczema in infancy could modify the course of atopic eczema and reduce the risk of developing asthma later in childhood. The ongoing study, details of which were presented today at the congress of the European Academy of Dermatology and Venereology in Italy, is at the forefront of new research to investigate potential benefits of long-term treatment using Elidel® (pimecrolimus) cream 1%.

It is estimated that up to 80% of children who suffer from the chronic skin condition atopic eczema subsequently go on to develop other related diseases such as allergic asthma and rhinitis (or "hay fever")1 a sequence known as the "atopic march". This widely-recognized disease progression is being investigated in a clinical trial called SAM (Study of the Atopic March), involving 1,100 infants aged 3-18 months who are currently being recruited at 20 centers in the US.

For the first 36 months of treatment in this study, investigators will assess the effect of long-term treatment with Elidel on the natural course of atopic eczema. Following this randomized, double-blind phase of the study, eligible participants will receive the non-steroid cream for a further 33 months on an open-label basis. On completion of the study, efficacy will be assessed in terms of the diagnosis and time of onset of asthma. Other signs of allergic sensitivity such as food allergies, allergic rhinitis, allergic conjunctivitis, and levels of the immune antibody IgE will also be evaluated.

The SAM study explores the hypothesis that Elidel-based long-term management of atopic eczema, starting in infants at the first manifestation of the disease, provides control of eczema, maintains integrity of the skin barrier function, and reduces penetration of allergens through the upper layers of the epidermis. This intervention is expected to normalize the exposure of immune-competent cells in the deeper layers of the epidermis, reducing their ability to mount an atopic immune response that could affect the development of atopic inflammation in other organs, such as asthma in the lungs (the so-called "atopic march").

Prof. Johannes Ring of the Department of Dermatology and Allergy, Biederstein, Technical University Munich, Germany, who presented details of the study design at EADV, said: "The aim is to determine whether use of topical calcineurin inhibitors at the first diagnosis of eczema reduces the incidence of asthma by the age of six. We know that atopic eczema is often the earliest manifestation of the atopic disposition, and it is important to investigate whether this type of early intervention may provide benefits not just by controlling atopic eczema through flare prevention, but also by offering the potential for disease modification in effect, halting the atopic march in its tracks."

Elidel and the quest for long-term control

The Study of the Atopic March builds on growing evidence from clinical trials and clinical experience that treatment with Elidel can help to control eczema and reduce the painful and distressing cycle of flare-ups that characterize the disease.

The need for long-term treatment strategies to control eczema is highlighted by the findings of ISOLATE, the International Study Of Life with ATopic Eczema,2 involving 2,000 patients and caregivers in eight countries. The results, revealed for the first time today at EADV, show that 75% of respondents believed that being able to control their eczema effectively would be the single most important improvement to their quality of life. In addition, 67% of patients and caregivers said that their preferred treatment option was to apply a non-steroid medication as early as possible to prevent flare-ups.

Evidence from clinical trials indicates that when applied at the first signs and symptoms of atopic eczema, Elidel prevents the progression to a full-blown flare-up and prolongs flare-free time, allowing topical corticosteroids to be reserved for use as rescue therapy in severe "breakthrough" flare-ups.

Another aspect of long-term treatment is being explored through an innovative clinical trial which aims to shed more light on a paradoxical aspect of the flare cycle namely that even after a flare-up has subsided and the skin appears normal, underlying inflammation is still present in patients with atopic eczema. The multi-center, double-blind study called PARADIGM will identify cellular and molecular changes in the post-lesional phase of eczema and assess the effect of Elidel. Skin biopsies will be taken from cleared or "normal" skin of 70 adult patients with mild or moderate atopic eczema, previously treated with either Elidel or a control, and compared with skin from non-atopic volunteers.

Prof. Giampiero Girolomoni of the Istituto Dermopatico dell'Immacolata, IRCCS, Rome, Italy, said: "It is clear that pre-emptive, long-term steroid-sparing strategies for the management of atopic eczema are long overdue. Given the opportunity, patients would welcome a new treatment approach in which their eczema and in particular, their flares-ups are controlled and occur at more extended intervals. Historically, physicians have relied on short-term "reactive" therapy involving topical steroids, but patients deserve a more proactive strategy that enables them to apply topical non-steroid treatment at the very first signs or symptoms of an eczema flare-up and control their disease in the longer-term."

About Elidel

Elidel (pimecrolimus) cream 1% is licensed for the short-term and intermittent long-term treatment of mild to moderate atopic dermatitis (AD), to prevent the progression of flares in both children and adults. Elidel is the only non-steroid treatment for atopic dermatitis that is clinically proven to prevent flare progression and improve disease control, without the side effects associated with conventional treatment using topical steroids.

Elidel may be used on all skin surfaces, including delicate areas such as the face, neck and skin folds, with no limits on duration or volume of use. The active ingredient is pimecrolimus, which is derived from ascomycin, a natural substance produced by the fungus *Streptomyces hygroscopicus var. ascomyceticus*. Pimecrolimus selectively blocks the production and release of cytokines from T-cells. These cytokines in the skin cause the inflammation, redness and itching associated with eczema.

Elidel, developed and marketed by Novartis, was first launched in 2002 and is now registered in around 90 countries.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as "could reduce", "will", "is expected", "aim", or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Elidel. 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 the actual results with Elidel to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Elidel will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. Any such results can be affected by, among other things, uncertainties relating to clinical trials, including uncertainties as to the results of the ongoing SAM trial, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, government, industry, and general public pricing pressures, as well as factors discussed in the Company'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 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.

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1

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2

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis honors scientists for outstanding contributions to research and development

Basel, November 15, 2004 Novartis honored nine scientists from the Novartis Institutes for BioMedical Research (NIBR), Pharma Development and Consumer Health division with the Novartis Leading Scientist Award, recognizing their exceptional contributions to research and development.

The *Novartis Leading Scientist Awards* granted this year for the seventh time are part of the company's global VIVA (Vision, Innovation, Value, Achievement) program, which was established in 1998 to promote creativity and innovation in research and development. The awards are designed to recognize outstanding contributions made by scientists working in research and development and carry a prize of CHF 25,000, as well as the right to use the title "*Novartis Leading Scientist*."

At the Novartis Institutes for BioMedical Research, the Leading Scientist Award is being granted to the following scientists: *Dr. Guido Bold* for his significant contributions to the identification and development of targeted anticancer agents such as PTK787; *Dr. Sabine Geisse* for her significant contributions in providing state-of-the-art experimental protein technologies which are key in early R&D; *Dr. Peter Ertl* for his development of user-friendly web based software tools which allow scientists to calculate important molecular properties and drug transport characteristics; *Dr. Stuart Bevan* for the establishing of genomic technologies for the discovery and validation of novel drug targets, which resulted in five Phase I compounds and two Phase II compounds; and *Dr. Gary Ksander* for his successful management of projects within Cardiovascular Research which among others lead to finding one inhibitor that is currently in development as a combination product with Diovan®.

"Research is at the very core of our mission at Novartis to discover and develop better medicines to help treat patients around the world," said Dr. Mark Fishman, Head of the Novartis Institutes for BioMedical Research. "On behalf of Novartis, I'd like to personally thank these individuals for their tremendous achievement."

In Pharma Development, the following three scientists are being honored with the Leading Scientist Award: *Dr. Kurt Forrer* for his outstanding contribution to the modernization and improvement of the analysis of Biotech Products; *Dr. John M. Kovarik* for his excellent work in the areas of pharmacokinetic and exposure-response modeling for compounds such as FTY 720, Simulect®, Certican®, and Neoral®; and *Dr. Jürgen Sigg* for his pioneering role in the development of novel liquid dosage forms.

"With these awards we recognize the exceptional contributions made by these scientists working in research and development," added Dr. Joerg Reinhardt, Global Head of Pharma Development.

In Consumer Health division, *Jean Steffan* from the Novartis Animal Health unit was granted the Leading Scientist Award for his contribution in the development of Atopica®, a key product of this unit.

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Femara® gains U.S. FDA approval as only post-tamoxifen treatment for early breast cancer

New treatment option the first to help postmenopausal women with early breast cancer remain cancer-free following adjuvant tamoxifen therapy

Basel, Switzerland, October 29, 2004 Femara® (letrozole) is the first therapy approved by the U.S. Food and Drug Administration (FDA) for the extended adjuvant treatment of postmenopausal women with early breast cancer who have received adjuvant (post-surgery) tamoxifen therapy for five years, Novartis announced today.

"Femara truly provides hope to women who have survived early breast cancer by offering them an improved chance of remaining cancer-free," said Diane Young, M.D., vice president and global head of Clinical Development at Novartis Oncology. "This priority review approval marks the first time that nearly 100,000 women who complete tamoxifen therapy each year will have a medical option to reduce their ongoing risk of breast cancer recurrence."

The term *extended adjuvant* describes the period following adjuvant (post-surgery) treatment with tamoxifen. Even years after breast cancer diagnosis and primary treatment, the ongoing risk of breast cancer recurrence remains significant for all patients. Globally, approximately one-third of women with estrogen receptor-positive early breast cancer experience a recurrence, and over half of those recurrences occur more than five years after surgery. While tamoxifen is beneficial for five years post surgery, if used beyond that period, the risks associated with it outweigh the benefits. Extended adjuvant treatment with Femara is the first therapy to effectively reduce ongoing risk of breast cancer recurrence.

The approval for the extended adjuvant indication was based on results from the landmark, international, independent MA-17 study, which included more than 5,100 postmenopausal women and was coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario, Canada, and supported by Novartis. Initial results were published in the *New England Journal of Medicine* in October 2003.

The study showed that Femara reduced the risk of cancer coming back, or disease-free survival, by 38% and significantly increased a woman's chance of staying cancer-free. This is particularly important because when breast cancer recurs, it has very often spread beyond the breast (metastatic disease), which can have serious consequences. Femara also greatly reduced the chance of breast cancer returning to another part of the body, or distant metastases, by 39%.

About Femara

Femara is a leading once-a-day oral aromatase inhibitor that is also indicated for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer and for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Not all indications are available in every country. Novartis has filed in the European Union for the indication of extended adjuvant treatment of early breast cancer in postmenopausal women who have completed adjuvant (post-surgery) tamoxifen therapy. In addition to the U.S., this indication is now approved in the United Kingdom, Switzerland, Mexico, Korea and other countries around the world. Femara is currently available in more than 80 countries worldwide.

Femara contraindications and adverse events

The most common adverse events experienced with Femara are hot flushes, arthralgia/arthritis and myalgia. Other commonly reported adverse reactions are: nausea, fatigue, anorexia, appetite increase, peripheral oedema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, alopecia, increased sweating, rash, myalgia, bone pain, arthritis/arthralgia, and weight increase.

Femara is contraindicated in women who are pregnant or breast-feeding as well as in women with premenopausal endocrine hormone receptor status. Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients.

The foregoing release contains forward-looking statements that can be identified by terminology such as "provides hope," "will have," "offering... improved chance," or similar expressions, or by express or implied discussions regarding potential future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will reach any particular sales levels. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company'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.

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Additional information regarding Femara or Novartis Oncology can be found on the websites www.femara.com or www.novartisoncology.com. Additional media information can be found at www.novartisoncologyvpo.com.

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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: December 2, 2004

By: /s/ MALCOLM B. CHEETHAM

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

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