NOVARTIS AG
Form 6-K
April 02, 2004

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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 March 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):

Yes: o No: ý

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. Strong Results of Lek in 2003 Drive Growth for Sandoz, the World's Second Largest Generic Company (Ljubljana, Slovenia, March 5 2004)

2. FDA approves Myfortic® to prevent organ rejection after kidney transplantation (Basel, 1 March 2004)

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Strong Results of Lek in 2003 Drive Growth for Sandoz, the World's Second Largest Generic Company

Dr. Vasella Highlights Important Role of Lek in Global Development Network of Sandoz

Ljubljana, Slovenia, March 5 2004 Novartis Chairman & CEO, Dr. Daniel Vasella, discussed the importance of Lek as a cornerstone in the global development network for generic medicines at a meeting held today at Lek's headquarters. Lek is part of Sandoz, Novartis' generic business and the world's second largest generic medicine company in the world.

"On the eve of it's entry into the EU, we believe Lek is a great example of a Slovenian company that has transformed itself from an important local company into a global center of excellence for one of the world's leading generic medicines companies," said Dr. Vasella. "Lek's long-term commitment to building strong competence in intellectual property as well as technical and engineering expertise led, in part, to their success in achieving outstanding business results in 2003."

Lek made a major contribution to the success of Sandoz, Novartis' generic business in 2003. Sandoz' (+60%; 47% in local currency) full-year sales were driven by the U.S. retail pharmaceuticals business and the successful integration of Lek.

In 2003, Lek created 300 new jobs, including 50 R&D positions, as the company continues to build competence in the areas of pharmaceutical formulations, active pharmaceutical ingredients and biopharmaceutical products.

"Successful growth allows for continued investment, which is leading to the creation of a new biopharmaceutical plant in Menge, Slovenia, as well as the creation of new solid dosage pharmaceutical plants in Poland and Romania," added Dr. Vasella.

"We are committed to Slovenia and to Lek and we continue to see Slovenia as an attractive market for foreign investment, based on the country's dynamic growth, low inflation and adoption of international legal standards," continued Dr. Vasella.

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and profound know-how make Sandoz a renowned partner in the Pharmaceuticals, Biopharmaceuticals and Industrial Products Franchises. Altogether, Sandoz employs approximately 13,000 people worldwide and posted sales of USD 2.9 billion in 2003.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's business achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 500 people and operate in over 140 countries around the world. For further information, please consult http://www.novartis.com.

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INVESTOR RELATIONS RELEASE

FDA approves Myfortic® to prevent organ rejection after kidney transplantation

Basel, 1 March 2004 Novartis Pharma AG announced today that the U.S. Food and Drug Administration has approved the use of Myfortic® (mycophenolic acid) delayed release tablets in combination with cyclosporine and corticosteroids to prevent organ rejection in kidney transplant patients.

Myfortic is a new, enteric-coated formulation of mycophenolate acid that delivers the active moiety mycophenolic acid (MPA). This is the same active moiety as delivered by mycophenolate mofetil (MMF, Cellcept®), which is taken by over 80% of new kidney transplant recipients in the United States as part of their immunosuppressive regimen.

"Myfortic in combination with Neoral® (cyclosporine for microemulsion) gives patients and physicians a treatment option that offers the full benefits of mycophenolic acid therapy in an enteric-coated formulation," Tony Rosenberg, Head, Transplantation and Immunology Business Unit, Novartis Pharma AG.

Studies have reported that up to 70% of patients taking MMF required at least one dose change due to drug related side effects. Patients who underwent an initial reduction in MMF dose were eight times more likely to suffer acute organ rejection than those who had not had a dose adjustment. For these patients, enteric-coated Myfortic is a new option.

Results of two global multi-center trials, in more than 700 patients, indicate that Myfortic and MMF are therapeutically equivalent in *de novo* renal transplant patients and that the conversion to Myfortic from MMF is safe in maintenance renal transplant patients.

Myfortic successfully completed the European Mutual Recognition Procedure (MRP) and was approved for the prevention of acute rejection in kidney allografts (transplants) in adult patients on February 7, 2004. It received its first regulatory approval, from Switzerland, in October 2002.

"The approval of an enteric-coated immunosuppressant like Myfortic is very exciting news for renal transplant patients," said Professor Robert Ettenger, MD, UCLA, Los Angeles. "Different products work for different patients. The availability of more treatment options increases the chances that we can reduce the risk of organ rejection in more patients."

The Novartis Transplantation and Immunology Team is committed to developing a new and innovative range of therapeutic products for the prophylaxis of organ rejection in order to provide the most extensive choice of drugs to the transplant community and to maintain Novartis' role as a global market leader in this field of medicine.

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This release contains "forward-looking statements," relating to the Company's business, which can be identified by the use of forward-looking terminology such as "indicate" "offers," "increases the chances," "is committed to," "to provide," "to maintain," or similar expressions, or by express or implied discussions regarding the marketing or potential futures sales of Myfortic. Such statements reflect the current views of the Company with respect to future events. There can be no guarantees that Myfortic will be commercialized in any market. Any such commercialization can be affected by, among other things, uncertainties relating to clinical trials, regulatory actions or delays or

government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, competition in general, increased government pricing pressures, as well as factors discussed 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 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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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 1, 2004

By: /s/ MALCOLM B. CHEETHAM

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

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