

NOVARTIS AG
Form 6-K
May 04, 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 April 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: ☒ 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: ☒

Enclosures:

1. Novartis drug Sandostatin® LAR® approved in Japan for acromegaly and symptoms of gastrointestinal hormone secreting tumors (Basel, Switzerland, 23 April 2004)
2. Sandoz Inc. launches GENERIC REBETOL® (Princeton, N.J., April 7, 2004)

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis drug Sandostatin® LAR® approved in Japan for acromegaly and symptoms of gastrointestinal hormone secreting tumors

Basel, Switzerland, 23 April 2004 Novartis announced today that the Japanese health authority has approved Sandostatin® LAR® (octreotide acetate for injectable suspension) for the treatment of acromegaly and pituitary gigantism which is unresponsive to or unsuitable for surgery or other drug therapies, and for symptoms associated with gastrointestinal hormone secreting tumors (also known as gastroenteropancreatic (GEP) neuroendocrine tumors (NET), including carcinoid tumors, gastrinomas, and VIPomas (Vasoactive Intestinal Peptide-secreting tumors).

The approval from the Japanese Ministry of Health, Labor and Welfare was based on clinical data from studies conducted in Japan and Western countries, including the member states of the European Union and the United States, where Sandostatin LAR is approved already. Sandostatin LAR is approved in more than 70 countries.

"Sandostatin LAR is the standard around the world for these conditions and we're pleased that the health authorities in Japan have approved the drug so patients in Japan can now benefit from it," said David Epstein, President, Novartis Oncology.

Clinical Data

The data from two Japanese trials, one in acromegaly and pituitary gigantism and the other in carcinoid syndrome, were consistent with findings of the previous western Phase III studies that were the basis for approval in the U.S. and E.U. In the western Phase III acromegaly studies, data showed that Sandostatin LAR was effective in reducing GH levels to <2.5ng/mL as the therapeutic goal in 89 out of 128 patients (69.5%). In addition, IGF-1 level was normalized in 85 out of 128 patients (66.4%). The drug markedly reduced clinical symptoms of acromegaly including headache, fatigue, perspiration, arthralgia, parathesias and carpal tunnel syndrome.

In the western Phase III clinical trials for malignant carcinoid syndrome, data from 93 patients, in whom subcutaneous treatment with Sandostatin Injection had adequately controlled clinical symptoms, Sandostatin LAR was shown to be as efficacious as Sandostatin Injection in controlling clinical symptoms.

About Sandostatin LAR

Sandostatin LAR (octreotide acetate for injectable suspension), launched in most major countries in 1998 and in the US in 1999 is a convenient, once-monthly injection with a well-established safety profile for superior control of both GH and normalization of IGF-1. Sandostatin LAR is indicated for long-term maintenance therapy in acromegalic patients for whom medical therapy is appropriate and who have been shown to respond to and can tolerate Sandostatin® (octreotide acetate) injection.

In acromegaly, Sandostatin LAR targets the tumor to control in four critical areas: 1) the site of tumor where hypersecretion starts, 2) GH secretion, 3) IGF-1 production, and 4) symptoms including headache, fatigue, perspiration, arthralgia, parathesias and carpal tunnel syndrome. Sandostatin LAR is also indicated to control symptoms, such as severe diarrhea and flushing, of functional GEP tumors (e.g. metastatic carcinoid tumors and vasoactive intestinal peptide-secreting tumors (VIPomas)) in patients who have responded to and tolerated subcutaneous injections of Sandostatin.

Contraindications and adverse events

In clinical studies of acromegaly, some patients experienced diarrhea, abdominal pain, flatulence, constipation, nausea, vomiting, pain at injection site, slow or irregular heart rate, and high or low blood sugar levels. In studies of carcinoid syndrome, some patients experienced nausea, abdominal pain, headache, dizziness, fatigue, flatulence, vomiting, pain at injection site, and low blood sugar levels.

The foregoing release contains forward-looking statements that can be identified by terminology such as "can now benefit" or similar expressions, or by express or implied discussions regarding potential new indications for Sandostatin LAR or regarding potential future sales of Sandostatin LAR. 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 actual results with Sandostatin LAR to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Sandostatin LAR will be approved for any additional indications in any market or will reach any particular sales levels. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Sandostatin LAR could be affected by, among other things, additional analysis of Sandostatin LAR 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 pricing pressures; and other risks and factors referred to in the Company'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.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses 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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Additional information can be found also at www.sandostatin.com and media materials at www.novartis oncology vpo.com.

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Investor Relations Release

SANDOZ INC. LAUNCHES GENERIC REBETOL®

Company Shares Exclusivity

PRINCETON, N.J., April 7, 2004 Sandoz Inc., a Novartis company, announced today it is launching generic Rebetol® (Ribavirin), which used in combination with interferon is indicated for the treatment of hepatitis C.

"As one of the first providers of Ribavirin, we are committed to delivering value to patients and to our customers by offering a lower-cost alternative for the treatment of hepatitis C," said John Sedor, President and Chief Executive Officer of Sandoz in North America. "People with hepatitis C who need this drug therapy will now be able to obtain it more readily and receive excellent patient support."

The U.S. Food and Drug Administration (FDA) awarded Sandoz shared exclusivity for Ribavirin in approving its Abbreviated New Drug Application (ANDA) to manufacture and market the product. Sandoz will market Ribavirin in 200 mg capsules in multiple-count bottles. The product will be manufactured at a Sandoz facility in Colorado using state-of-the-art isolation suite technology.

Hepatitis C virus is one of the leading causes of chronic liver disease in the U.S., according to the National Institutes of Health. Hepatitis C affects more than four million Americans, the majority of whom are still undiagnosed and untreated.

According to IMS data, 2003 sales for Rebetol® reached \$645 million. Rebetol® is a registered trademark of Schering-Plough.

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. In the U.S., Sandoz Inc., is one of the largest prescription generic pharmaceutical companies. The company produces more than 200 products each year. Sandoz products range across many therapeutic drug categories including anti-infectives, anti-arthritis, cardiovasculars, gastrointestinal agents and psychotherapeutics. More information about Sandoz U.S. operations can be found at <http://www.us.sandoz.com>. Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses 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 research and development. 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>.

This release contains certain "forward-looking statements" relating to the Group's business, which can be identified by the use of forward-looking terminology such as "coming on stream", "will be", "to become", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations. Such statements reflect the current plans or views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, and other risks referred to in Novartis AG's 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 described herein as anticipated, believed, estimated or expected.

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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 30, 2004

By: /s/ MALCOLM B. CHEETHAM

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

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