NOVARTIS AG
Form 6-K
September 26, 2003

QuickLinks -- Click here to rapidly navigate through this document

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 September 25, 2003
(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

Novartis International AG
Novartis Communications
CH-4002 Basel

Switzerland

Tel +41 61 324 2200
Fax +41 61 324 3300
Internet Address:
http://www.novartis.com

MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

FDA requests additional data on arthritis and pain drug, lumiracoxib

Basel, 23 September 2003 Novartis announced today, that the US Food and Drug Administration (FDA) has requested the submission of the final report of the ongoing TARGET study as well as additional clinical data for lumiracoxib* for the indications of osteoarthritis and acute pain before marketing approval in the US may be granted. Ongoing clinical studies may in part address the information requested by the FDA.

Novartis aims to submit the full TARGET study report and the additional clinical data requested by the FDA as soon as possible. The timing of submission to resolve the non-approvability issues raised by the FDA will depend on the clarification of the FDA's precise requirements. However, a US launch of lumiracoxib is not anticipated before 2005.

"We will work very closely with the FDA to provide all necessary data and are committed to making this medicine available to patients," said Jörg Reinhardt, Head of Global Development, Novartis Pharma AG. "We believe the full analysis of TARGET as well as the additional clinical data will provide insights into the appropriate treatment of arthritis and pain and the risk/benefit profile of lumiracoxib."

On 16 September 2003 the Medicines and Healthcare Products Agency in the UK approved lumiracoxib for the symptomatic relief of osteoarthritis at 100-200 mg daily. In addition, lumiracoxib 400 mg daily received approval in the UK for the short-term relief of moderate to severe acute pain associated with primary dysmenorrhea, dental surgery and orthopaedic surgery.

This release contains certain forward-looking statements which can be identified by the use of forward-looking terminology, such as "may be granted," "may in part," "aims to," "will work," "believe," "will provide," or similar expressions, or by express or implied discussions regarding potential future regulatory filings regarding lumiracoxib, or potential future approvals of lumiracoxib. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the 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 FDA's stated and other regulatory requirements regarding lumiracoxib, or that lumiracoxib will be approved by the FDA for any indication. In addition, management's expectations regarding lumiracoxib could be affected by, among other things, uncertainties relating to product development, including the results of the ongoing TARGET trial and other trials, including clinical trials which must be conducted in the future in order to satisfy FDA's requirements; regulatory actions or delays, or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; increased government pricing pressures; and competition in general; as well as factors discussed in the Company's Form 20-F filed with the 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 AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult http://www.novartis.com.

# # #

*recently approved in the UK under the brand name Prexige®

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: September 25, 2003

By: /s/ MALCOLM B. CHEETHAM

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

QuickLinks