

NOVARTIS AG
Form 6-K
May 03, 2006

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 May 2, 2006

(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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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: ☒

Investor Relations

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- Investor Relations Release -

US submission of Exforge® accepted for review by the FDA as a new therapy option for high blood pressure

Exforge a single-tablet containing the leading antihypertensive medicines amlodipine (CCB) and valsartan (ARB)

Regulatory submission includes results from more than 5,000 hypertensive patients

Basel, April 27, 2006 Novartis announced today that the new drug application (NDA) for Exforge® (amlodipine besylate/valsartan) was accepted for standard review by the US Food and Drug Administration (FDA) as a new treatment option for people with high blood pressure. The submission for EU approval was completed earlier in 2006.

In clinical trials, Exforge demonstrated clinically significant blood pressure reductions. Exforge utilizes two complementary mechanisms of action through the calcium channel blocker (CCB) amlodipine and the angiotensin receptor blocker (ARB) valsartan. Both agents are the No. 1 prescribed branded medications in their respective classes.

More than 65 million Americans, or one in three adults, are estimated to have high blood pressure, with approximately 70% of them not under control. Among people who are treated for hypertension, approximately 50% are still estimated not to have achieved their treatment blood pressure goal.

With so many patients still uncontrolled, a real need exists for an agent that can help people reach and maintain their blood pressure goal, said Dr. James Shannon, Head of Development, Novartis Pharma AG. Exforge has the added benefit of bringing together the efficacy of two established mechanisms of action, resulting in significantly lower blood pressure.

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The US filing was based on a robust clinical trial program involving more than 5,000 hypertensive patients. The program included five controlled trials in which more than 2,600 patients received Exforge once daily. A single daily dose of Exforge provided clinically significant blood pressure reductions and was well tolerated.

High blood pressure is the world's most common killer, affecting at least 25% of all adults⁽¹⁾. Researchers estimate that the disease affects about one billion people globally⁽²⁾. High blood pressure affects and damages arteries in the body, which can burden the heart, kidney, brain and other vital organs and blood vessels. Failing to control high blood pressure can cause heart attacks, strokes, heart and kidney failure as well as premature death. An estimated seven out of ten people with high blood pressure fail to reach their blood pressure targets, with many needing multiple agents to maintain their blood pressure goal^{(3),(4)}.

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 "new therapy/ treatment option," or similar expressions, or by express or implied discussions regarding potential marketing approvals or potential future sales of Exforge. Such statements reflect the current views of the Group with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Exforge will be approved for any indications in any market, nor that it will reach any particular sales levels. In particular, management's expectations regarding Exforge could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of Exforge clinical data or new clinical data; 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.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group's businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) Kearney et al *Lancet* 2005; 365: 217-223
- (2) The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December 2003, p2
- (3) Brown et al *Journal of Human Hypertension* 2003; 17, 81-86
- (4) The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December 2003, p4

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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: May 2, 2006

By: /s/ MALCOLM B. CHEETHAM

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