NOVARTIS AG
Form 6-K
May 15, 2009

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 14, 2009

(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: x 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**: x

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**: x

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**: x

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- Investor Relations Release -

Novartis receives approval from FDA to market Prevacid® 24HR as first and only OTC proton pump inhibitor in original prescription formulation

- *This approval will provide greater convenience and broader access to an effective treatment option to the 50 million Americans(1) suffering from frequent heartburn*

- *Once-daily, prescription-strength Prevacid® 24HR is the first OTC proton pump inhibitor approved for the treatment of frequent heartburn in the US since 2003*

- *Prescription-strength Prevacid 24HR treats frequent heartburn for a full 24 hours*

Basel, Switzerland, May 14, 2009 Novartis announced today that Prevacid® 24HR (lansoprazole delayed-release capsules 15 mg) has been approved by the US Food and Drug Administration (FDA) as the first over-the-counter (OTC) Proton Pump Inhibitor (PPI) for the treatment of frequent heartburn since 2003. Prevacid 24HR is expected to be available over-the-counter in 2009.

Once-daily Prevacid 24HR is the first OTC PPI approved in its original prescription formulation. It is the only PPI containing the active ingredient lansoprazole to be approved for OTC treatment of frequent heartburn, which is defined as heartburn that occurs two or more days per week. In three clinical studies, Prevacid 24HR demonstrated significantly better efficacy in treating frequent heartburn than placebo. Although some people experienced complete relief of symptoms within 24 hours, it may take one to four days for full effect.

The prescription medicine Prevacid® (lansoprazole)(2), a brand that 21 million patients have trusted to treat their acid-related disorders(3), is one of the top five prescription brands in the US in terms of total prescription dollar sales(4). The drug achieved $3.37 billion in annual sales in the US in 2008(5). Novartis has licensed the Prevacid® trademark and certain other intellectual property rights for OTC development and commercialization from Takeda Pharmaceuticals North America, Inc.

Our partnership with Takeda Pharmaceuticals on this switch has been outstanding, said Larry Allgaier, Global Head of the Novartis OTC Business Unit. Takeda Pharmaceuticals trusted Novartis to take this leading product over-the-counter because of our core competencies as a pharmaceutical company, and our demonstrated history of success taking prescription products over the counter, providing consumers with greater convenience and broader access to the effective treatments they need, while continuing to build the brands.

Prescription-strength Prevacid 24HR treats frequent heartburn for a full 24 hours. Prevacid 24HR works by stopping the release of acid into the stomach.

This is an important development for the 50 million American adults who suffer from frequent heartburn, said M. Brian Fennerty, MD, Professor of Medicine, Division of Gastroenterology,

Oregon Health and Science University. Prescription strength Prevacid 24HR will be both an effective and well-tolerated option for treating frequent heartburn.

The FDA approved Prevacid 24HR in the form of 15mg delayed-release capsules. Prevacid 24HR is a 14-day course of treatment and should be taken once per day before eating in the morning to treat frequent heartburn.

For more information about Prevacid 24HR visit www.Prevacid24HR.com.

About Frequent Heartburn

More than 50 million Americans suffer from frequent heartburn, which is defined as heartburn occurring two or more days per week. Frequent heartburn is a result of the backing up of stomach acid into the esophagus. Typically the lower esophageal sphincter muscle opens to allow food to pass, but then quickly closes. However, in frequent heartburn sufferers the muscle relaxes and allows food and acid from the stomach to travel back up into the esophagus. As a result, sufferers often have a burning sensation in the chest and/or throat, a sour or bitter taste in the mouth, difficulty swallowing, chronic coughing and wheezing or other asthma-like symptoms. These symptoms of frequent heartburn can become worse when one is lying down or bending over.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, expected, or similar expressions, or by express or implied discussions regarding the potential date on which Prevacid® 24HR will be available for sale over-the-counter or regarding potential future revenues from Prevacid® 24HR. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Prevacid® 24HR to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Prevacid® 24HR will be available for sale over-the-counter on any particular date. Nor can there be any guarantee that Prevacid® 24HR will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Prevacid® 24HR could be affected by, among other things, competition in general; government, industry and general public pricing pressures; unexpected regulatory actions or government regulation generally; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in Novartis AG 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.

About Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

# # #

References

(1) National Heartburn Alliance: http://www.heartburnalliance.org/ heartburn_assessment.php

(2) Prevacid® is a registered trademark of Takeda Pharmaceuticals North America, Inc., and is used under license by Takeda Pharmaceuticals North America, Inc.

(3) SDI Total Patient Tracker (TPT) 2002-2008

(4) SDI VONA 12-months ending December 31, 2008

(5) IMS NPA 12-months ending December 31st, 2008

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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 14, 2009

By: /s/ MALCOLM B. CHEETHAM

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