

NOVARTIS AG  
Form 6-K  
February 09, 2010

# 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 February 9th, 2010**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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:

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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:

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**Novartis International AG**

Novartis Global Communications

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Switzerland

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**- Investor Relations Release -**

**Novartis gains exclusive rights to Debio 025, an antiviral agent in Phase IIb development as potential first-in-class hepatitis C therapy**

- *Phase II results demonstrate efficacy of Debio 025, a cyclophilin inhibitor, against hepatitis C virus when used alone or in combination with current standard therapy(1)*
- *Cyclophilin inhibitors evolving as new class of medicines with potential to become part of future standard of care for treating hepatitis C*
- *Hepatitis C is one of the world's most common liver diseases, current therapies may only be effective in around 50% of patients(2)*
- *Novartis to make upfront payment to Debiopharm Group, with Debiopharm eligible for milestones and royalties on future sales*

**Basel, February 9, 2010** Novartis has gained exclusive rights to develop and market Debio 025 (alisporivir), a potential first-in-class antiviral agent currently in Phase IIb development for the treatment of hepatitis C. Debio 025 is the first in a new class of drugs called cyclophilin inhibitors which could become part of the future standard of care for the disease.

Debio 025 has been in-licensed from Debiopharm Group, an independent biopharmaceuticals company based in Switzerland, under an agreement which gives Novartis exclusive worldwide development and marketing rights (excluding Japan). Under the terms of the agreement, Novartis will make an upfront payment to Debiopharm, and Debiopharm will be eligible for milestone payments, and for royalties on future sales of Debio 025, if it is approved. The transaction is subject to customary regulatory approvals.

Hepatitis C is sometimes referred to as a "silent epidemic" because the virus can lie dormant in the body for years or even decades before the symptoms become apparent, said David Epstein, CEO of the Novartis Pharmaceuticals Division. Novartis is dedicated to developing medicines that will reduce the impact of this disease on patients, and we believe that Debio 025 could prove an important step forward by significantly

enhancing the efficacy of existing therapy that forms the standard of care for hepatitis C.

More than 170 million people worldwide are infected with hepatitis C virus (HCV)(3), and this can cause serious liver disease leading to cirrhosis or liver cancer which may result in death. There is an urgent need for more effective medications, often used in combination, as current therapy is only effective in around 50% of patients with the most prevalent form of the virus, called genotype 1(2).

Cyclophilin inhibitors such as Debio 025 provide a novel approach to treatment by targeting host proteins that are involved in the growth of the hepatitis C virus. Results of a Phase II study show that Debio 025 significantly reduced HCV replication when used alone, and had an important

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additive anti-HCV effect (4.6 log<sub>10</sub> reduction) in combination with pegylated interferon alfa-2a in treatment-naïve patients(1). No significant safety issues have been identified so far.

A double-blind, placebo-controlled Phase IIb study is now under way to assess the efficacy and safety of Debio 025 in combination with the current standard of care for hepatitis C – peginterferon alfa-2a plus ribavirin – in treatment-naïve patients. The study is being conducted in patients with the most common genotype 1. Debio 025 is also effective against other genotypes of the virus(1),(4).

The in-licensing of Debio 025 represents a further expansion of the Novartis hepatitis C portfolio following the filing of Joulferon®/Zalbin® (albinterferon alfa-2b) for European and US regulatory approval at the end of 2009. In Phase III studies, Joulferon dosed every two weeks showed similar efficacy to peginterferon alfa-2a dosed weekly while requiring half the number of injections. Albinterferon alfa-2b is being developed and will be co-commercialized in the US together with Human Genome Sciences, who filed for US approval under the brand name Zalbin®.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, eligible, could, will, can, dedicated, believe, may, or similar expressions, or by express or implied discussions regarding potential regulatory approval of Novartis acquisition of rights to Debio 025, potential marketing approvals for Debio 025, or for Joulferon/Zalbin, or regarding potential future revenues from such products. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Novartis will receive the necessary regulatory approvals to complete its acquisition of the rights to Debio 025. Nor can there be any guarantee that Debio 025 or Joulferon/Zalbin will be approved for sale in any market. Nor can there be any guarantee that these products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; 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 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 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.



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**References**

- (1) Flisiak R, *et al.* The cyclophilin inhibitor Debio 025 combined with PEG IFNalpha2a significantly reduces viral load in treatment-naïve hepatitis C patients. *Hepatology* 2009;49 (5):1460-8.
- (2) Hoofnagle JH. A step forward in therapy for hepatitis C. *N Engl J Med.* 2009;360 (18):1899-901.
- (3) Lauer GM, Walker BD. Hepatitis C virus infection. *N Engl J Med.* 2001;345 (1):41-52.
- (4) Flisiak R, *et al.* The cyclophilin inhibitor Debio-025 shows potent anti-hepatitis C effect in patients coinfecting with hepatitis C and human immunodeficiency virus. *Hepatology.* 2008;47(3):817-26.

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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: February 9th, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting

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