

NOVARTIS AG  
Form 6-K  
May 19, 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 19, 2009**

(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:

**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:

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis announces restructuring of global collaboration with Schering-Plough to develop fixed-dose combination respiratory therapies**

- *Novartis assumes exclusive worldwide development and marketing rights for investigational once-daily QMF149 being developed for COPD and asthma*
- *QMF149 combines QAB149 (indacaterol) with mometasone and is presently being developed on Schering-Plough's Twisthaler® inhalation system*
- *Agreement marks an important step for Novartis toward a potential innovative respiratory portfolio centered around QAB149 (indacaterol)*
- *Respiratory diseases, such as chronic obstructive pulmonary disease (COPD) and asthma, have enormous health and economic costs*

**Basel, May 19, 2009** Novartis has assumed exclusive worldwide rights to develop and commercialize QMF149, a fixed-combination of its investigational QAB149 (indacaterol) with Schering-Plough Corporation's inhaled corticosteroid mometasone, in changes announced today to the companies' collaboration to develop fixed-dose combination respiratory therapies.

In development for chronic obstructive pulmonary disease (COPD) and asthma, QMF149 combines the anti-inflammatory properties of mometasone with the bronchodilation of QAB149, a long-acting beta2-adrenergic agonist.

Novartis is seeking to build a portfolio of innovative respiratory treatments centered around indacaterol to relieve suffering from COPD and asthma, two of the most prevalent respiratory ailments, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. This strengthens our strategic capabilities to develop key respiratory health solutions to people with respiratory diseases.

The changes are the latest development in a successful long-term relationship between Novartis and Schering-Plough that dates back to 2002. Since August 2006, when the collaboration was expanded to jointly develop and commercialize a fixed-dose combination of QAB149

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(indacaterol) and mometasone, this collaboration has completed the formoterol/mometasone combination's phase II (asthma, COPD) and phase III (asthma) development, while phase II development of QAB149 (indacaterol)/mometasone (asthma, COPD) continues.

Under the new agreement with Schering-Plough, Novartis assumes exclusive worldwide rights to develop and commercialize QMF149. Schering-Plough assumes exclusive rights to develop and commercialize a fixed-combination of mometasone plus the Novartis product Foradil® (formoterol), another long-acting **beta2-adrenergic agonist**.

Novartis will assume the remaining development and commercialization costs for the QAB149 (indacaterol)/mometasone combination, including use of the Twisthaler® device, while the remaining development and future commercialization costs of the formoterol/mometasone combination, including use of a pMDI device, will be borne by Schering-Plough. There will be a royalty sharing arrangement based on sales. Novartis will also recognize sales worldwide for QMF149 upon commercialization.

QAB149 (indacaterol) is currently under regulatory review. In December 2008, Novartis submitted regulatory dossiers for approval of indacaterol in the United States and the European Union. Mometasone and formoterol are currently marketed under the trade names Asmanex® and Foradil®, respectively.

This transaction is subject to customary regulatory approvals.

### **About COPD and asthma**

Chronic obstructive pulmonary disease (COPD) is a leading cause of death that is growing in prevalence. Affecting more than 210 million people worldwide, COPD accounts for nearly 3 million deaths each year. The primary cause of COPD is tobacco smoke (through tobacco use or second-hand smoke). It is also a leading cause of productivity losses through missed work days.

Asthma is a chronic inflammatory lung disease that affects more than 300 million people worldwide. The health and quality of life for these patients are often severely affected, with more than 180,000 people believed to die each year from asthma-related complications.

### **Important Safety Information**

Foradil®, belongs to a class of medications known as long-acting beta2-adrenergic agonists or LABAs. In patients with asthma, LABAs may increase the chance of asthma related death. Therefore, Foradil® should only be used as additional therapy for patients not adequately controlled on other asthma controller medications.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to develop, investigational, being developed, to develop and commercialize, in development, seeking, will, future, may, or similar expressions, or by express or implied discussions regarding potential new marketing approvals for QMF149 or QAB149, potential future combination products containing Foradil, a potential future Novartis respiratory portfolio, or regarding potential future revenues from QMF149, QAB149, or Foradil or from any such respiratory portfolio. 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 QMF149 or QAB149 will be approved for sale in any market. Nor can there be any guarantee that any future combination products including Foradil will be approved for sale in any market. Neither can there be any guarantee that Novartis will successfully bring to market any respiratory portfolio centered around QAB149 or any other products. Nor can there be any guarantee that any of the products or the potential portfolio referred to in this release will achieve any particular levels of revenue in the future. In particular, management's expectations regarding such products and such potential portfolio 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

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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>.

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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 19, 2009

By: /s/ MALCOLM B. CHEETHAM

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