

NOVARTIS AG  
Form 6-K  
September 16, 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 September 15, 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:

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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):

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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  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis investigational bronchodilator QAB149 improves lung function and reduces breathlessness compared to tiotropium in patients with COPD**

- *New data show a higher proportion of patients treated with QAB149 achieved clinically relevant improvements in symptoms of breathlessness compared to tiotropium(1)*
- *Patients taking QAB149 experienced 20 percent more days free of relief medication, used to treat acute episodes of severe breathlessness, compared to tiotropium(2)*
- *The Phase III data reinforce that once-daily QAB149 combines relevant 24-hour bronchodilation(3),(4) with an onset of action within five minutes(5)*

**Basel, September 15, 2009** Novartis announced today results from Phase III trials showing QAB149 (indacaterol), an investigational once-daily bronchodilator for chronic obstructive pulmonary disease (COPD), significantly improves lung function(3) and provides a significant reduction in breathlessness(1) compared to tiotropium, a current treatment option. The data were presented this week at the European Respiratory Society (ERS) 2009 Annual Congress in Vienna, and build on those presented at the American Thoracic Society (ATS) Annual Meeting earlier this year.

QAB149 has the potential to be recognized as the best bronchodilator for COPD by providing patients with significantly greater lung function improvement and reductions in breathlessness compared to other bronchodilators, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. We also plan for QAB149 to form the foundation of a new portfolio of products, designed to improve patients' respiratory health.

At 12 weeks of treatment, QAB149 150 µg and 300 µg improved trough FEV<sub>1</sub>(1), a key measure of lung function, by 50 ml and 40 ml respectively over tiotropium 18 µg ( $p \leq 0.01$ )(3). New data show at week 26, that patients on QAB149 300 µg continued to show greater improvement in trough FEV<sub>1</sub> than tiotropium ( $p < 0.05$ )(3).

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Further new data shows that a higher proportion of patients treated with QAB149 achieved a significant clinically relevant improvement in their symptoms of breathlessness compared to tiotropium(1). Patients on QAB149 also had a highly significant greater than 20 percent increase in days during which no relief medication, therapy used to treat acute episodes of severe breathlessness, was required compared to patients treated with tiotropium(2).

If approved, QAB149 would become the first once-daily bronchodilator to combine clinically relevant 24-hour bronchodilation(3),(4) with onset of action within five minutes(5). QAB149 is currently

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undergoing regulatory review in the European Union, the United States and other countries around the world for the treatment of COPD.

As most COPD patients want to remain active, we need new therapy options that alleviate some of the lifestyle compromises patients are forced to make due to their COPD, said Professor Ronald Dahl, University Hospital of Aarhus, Denmark. These indacaterol data in effect mean that the improvements in lung function are accompanied by important quality-of-life improvements that our patients need.

Data presented on all evaluated doses of QAB149 highlights a good overall safety and tolerability profile(6),(7). The most common adverse drug reactions were nasopharyngitis, cough, upper respiratory tract infection, and headache. These were mild or moderate in the vast majority of cases and became less frequent if treatment was continued.

COPD is a progressive, life-threatening respiratory disease(8) that affects 210 million people worldwide(9). Commonly caused by cigarette smoke and other harmful fumes, COPD is characterized by a persistent obstruction of airflow in the lungs, resulting in breathlessness(8). According to the World Health Organization, COPD is currently projected to become the third leading cause of death worldwide by 2030(10). Bronchodilators are a group of drugs that widen the airways in the lungs. While incurable, COPD is manageable and improving airflow with the use of long-acting bronchodilators is central to symptomatic relief(11).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, plan, designed to, would, projected, or similar expressions, or by express or implied discussions regarding potential marketing approvals for QAB149 (indacaterol) or of a potential Novartis portfolio of respiratory products 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 with QAB149 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that QAB149 or any other potential components of a Novartis portfolio of respiratory products will be approved for sale in any market. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding such 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; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 each of 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 99,000 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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**Novartis Media Relations**

**Central media line :** +41 61 324 2200

**Eric Althoff**

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

**Rebecca Fisher-Pollard**

Novartis Pharma Communications

+41 61 324 91 66

+41 79 426 46 84

rebecca.fisher-pollard@novartis.com

**Novartis Investor Relations**

**Central phone:**

Ruth Metzler-Arnold

Pierre-Michel Bringer

John Gilardi

Thomas Hungerbuehler

Isabella Zinck

+41 61 324 7944

+41 61 324 9980

+41 61 324 1065

+41 61 324 3018

+41 61 324 8425

+41 61 324 7188

**North America:**

Richard Jarvis

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**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 15, 2009

By: /s/ MALCOLM B. CHEETHAM

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

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