NOVARTIS AG
Form 6-K
May 26, 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 21, 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

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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: o **No:** x

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- Investor Relations Release -

Phase III data show Novartis investigational bronchodilator QAB149 significantly improves lung function over current treatments in COPD(1),(2)

- *Once daily QAB149 (indacaterol) significantly improves lung function compared to formoterol and tiotropium, two currently approved COPD treatments, at three months of treatment(1),(2)*
- *Pending approval, QAB149 could be the first once-daily bronchodilator to combine clinically relevant 24-hour bronchodilation with onset of action within five minutes(3),(4),(5)*
- *All doses of QAB149 are well-tolerated with a good overall safety profile in three pivotal trials: INVOLVE (1 year), INHANCE (6 months) and INLIGHT-1 (3 months)(4),(5),(6)*
- *COPD, a debilitating and progressive respiratory disease, is a leading and growing cause of death that affects 210 million people worldwide(7)*

Basel, May 21, 2009 Initial results from three pivotal phase III trials show the Novartis investigational bronchodilator QAB149 (indacaterol) could deliver clinically relevant(1) lung function improvements, within five minutes of the first dose, lasting for 24 hours in patients with chronic obstructive pulmonary disease (COPD)(3),(4),(5).

The data presented at the American Thoracic Society (ATS) 2009 International Conference in San Diego show that QAB149, a long-acting beta2-agonist (LABA), significantly improved lung function from the first day of therapy to up to one year of treatment(1). The data also reveal that all evaluated doses of QAB149 were well-tolerated and had a good overall safety profile(4),(5),(6).

All doses of once-daily QAB149 met the primary efficacy endpoint of significant improvement in FEV1 (forced expiratory volume in one second) versus placebo at twelve weeks.(3),(4),(5) This improvement was seen as early as five minutes post-dose and at every subsequent time point measured in each study(3),(4),(5). In INVOLVE QAB149 (300µg and 600µg) also showed significant improvements over formoterol 12µg in trough FEV1 difference versus placebo at three months (170ml and 170ml vs. 70ml; $p<0.001$), and at one year (160ml and 150ml vs. 50ml; $p<0.001$)(1).

In addition to data presented at ATS, Novartis released data today showing that at 12 weeks, QAB149 (150µg and 300µg) achieved additional improvements of 50ml and 40ml, respectively, versus open-label tiotropium 18µg, in trough FEV1 or 24-hour post-dose forced expiratory volume in one second(2). Further presentation of study results is planned for later this year.

(1) Defined as >120mL more than placebo in forced expiratory volume in one second (FEV1) a standard measure of lung function.

Bronchodilator treatment is the first-line approach for the symptomatic management of patients with COPD, and long-acting bronchodilators have a number of advantages, said Professor Stephen I. Rennard, Pulmonary and Critical Care Medicine, University of Nebraska Medical Center. The indacaterol data presented at ATS show that bronchodilation on a once-daily basis may be an important addition to the current therapeutic armamentarium in COPD.

COPD is a progressive, life-threatening respiratory disease that affects 210 million people worldwide(7),(8). 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(9). Bronchodilators are a group of drugs that widen the airways in the lungs. While COPD is incurable, improving airflow with the use of long-acting bronchodilators is central to symptomatic management(10).

Novartis is committed to developing a range of therapies for patients with respiratory diseases such as COPD, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. QAB149 could become the foundation of a portfolio of medicines that aims to improve peoples respiratory health.

QAB149 is currently undergoing regulatory review in the European Union and the United States. If approved, QAB149 could become the foundation of a Novartis portfolio of products, including fixed-dose combinations, designed to address unmet needs in respiratory care.

Further study results

In the one-year INVOLVE study, QAB149 showed improved symptom control (cough, wheezing, breathlessness and sputum production and color) over twice-daily formoterol(11). In addition, treatment with QAB149 significantly prolonged the time to first COPD flare-up (exacerbation) compared to placebo(12).

The most commonly-reported adverse effects were nasopharyngitis, upper respiratory tract infection, headache and cough following inhalation, which was generally well-tolerated and did not result in different discontinuation rates between patients experiencing and not experiencing cough.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as could, planned, may, committed, aim to, designed to, or similar expressions, or by express or implied discussions regarding potential marketing approvals for QAB149 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 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 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

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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 21, 2009

By: /s/ MALCOLM B. CHEETHAM

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