NOVARTIS AG
Form 6-K
March 10, 2011

# 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 March 9, 2011**

**(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:** x Form 40-F: o

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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

**Novartis International AG**

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**- Investor Relations Release -**

**FDA advisory committee recommends US approval of Novartis once-daily bronchodilator QAB149 for COPD**

- *Phase III program demonstrated significant improvement in lung function lasting for 24 hours and supported safety and tolerability profile of QAB149(1)*

- *COPD is a progressive and life-threatening lung disease that affects more than 12 million Americans(2) and is a major cause of long-term disability(3)*

**Basel, March 9, 2011** An advisory committee recommended today that the Food and Drug Administration (FDA) approve QAB149 (indacaterol) in the US as the first once-daily long-term maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

The committee voted 13 to four in favor of recommending approval of the 75 mcg dose. The advisory committee also voted 12 to five against recommending approval of the 150 mcg dose. The 75 mcg dose was seen as effective as the 150 mcg dose and the committee endorsed the safety of both doses.

The recommendation by the Pulmonary-Allergy Drug Advisory Committee (PADAC) followed a request from the FDA to further explore the efficacy and safety of lower doses of QAB149, an investigational medicine in the long-acting beta2-agonist (LABA) class.

The FDA has the option of seeking the advice of its advisory committees when it is reviewing a new drug for approval, although it is not obliged to follow the committee s recommendations.

Novartis is committed to addressing the needs of patients with COPD and we are encouraged by the advisory committee s recommendation for approval of QAB149, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. The company is focused on bringing innovative, safe and effective treatment options to patients and physicians, and we will work closely with the FDA as it completes its review of

QAB149.

The advisory committee reviewed an extensive program of clinical trials in which the efficacy of QAB149 at 75 and 150 mcg was studied in a total of 1,282 COPD patients in five key Phase III trials lasting 12-26 weeks. Results showed that both doses of QAB149 significantly improved lung function compared to placebo(1). These improvements were seen five minutes after the first dose and lasted for 24 hours(1).

The clinical trial program supporting US submission evaluated safety in 4,764 patients who received QAB149 for at least 12 weeks at doses of 75 mcg and greater, with results supporting the safety and tolerability profile of QAB149. The most commonly reported adverse events with both the 75 and 150 mcg doses were worsening of COPD, nasopharyngitis, cough, and headache(1).

We must intensify our efforts to increase awareness, prevention and detection, and to develop new treatments to help reduce the enormous burden COPD places on patients, their families and our healthcare system, said John W. Walsh, president and co-founder of the US-based COPD Foundation. Deaths from COPD are increasing much faster than previously projected, which should be a wake-up to all of us.

QAB149 is approved at 150 and 300 mcg once-daily doses in more than 50 countries worldwide under the brand-name Onbrez® Breezhaler®. Altogether, the clinical trial program for QAB149 involved more than 15,000 people of whom 9,243 were given QAB149 at varying doses and assessed for safety(1). Incremental efficacy benefits have been observed with indacaterol in escalating doses from 75 mcg up to 300 mcg, with higher doses showing increasing benefit for patients(4),(5).

In the US, Novartis is seeking approval for the use of QAB149 as a once-daily long-term maintenance bronchodilator treatment for airflow obstruction in patients with COPD, including bronchitis and/or emphysema. Novartis is not seeking an indication for asthma. If approved in the US, the proposed brand name will be Arcapta Neohaler .

COPD, a progressive and life-threatening lung disease making it difficult to breathe(6), affects more than 12 million people in the US, while another 12 million people are estimated to have the disease but are undiagnosed(2). COPD ranks as the third leading cause of death in the US(1)(7),(8) and is a major cause of serious long-term disability(3). Worldwide, COPD is estimated to affect a total of 210 million people(9).

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as recommends, recommended, recommending, recommendation, recommendations, committed, focused, will, projected, seeking, or similar expressions, or by ex
implied discussions regarding potential marketing approvals for QAB149 or regarding potential future revenues from QAB149. 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 will be approved for sale in the US or in any additional market, or regarding the timing of any such approvals. Nor can there be any guarantee that QAB149 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding QAB149 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.

(1) Preliminary 2008 US mortality rates for chronic lower respiratory diseases (CLRD), such as chronic bronchitis, emphysema, and bronchiectasis (Centers for Disease Control and Prevention).

**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 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon 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**

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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**

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| Date: March 9, 2011 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |