NOVARTIS AG
Form 6-K
March 24, 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 23, 2011

(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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Yes: o **No**: x

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 -

FDA informs Novartis of extension to US regulatory review period for QAB149, a novel once-daily bronchodilator for treatment of COPD

- *US Food and Drug Administration (FDA) extends review period for new drug application (NDA) by three months to July 2011*

- *Additional time requested to complete review of the large amount of data from comprehensive clinical trial program*

Basel, March 23, 2011 Novartis announced today that the US Food and Drug Administration (FDA) has extended the regulatory review period for QAB149 (indacaterol) for the 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 FDA asked for a three-month extension in order to complete its review of the new drug application (NDA) for QAB149 by July 2011. In its notification, the FDA said it needed more time to examine the data submitted by Novartis in support of the application. The agency did not request additional data.

This three-month extension reflects discussion at the advisory committee based on the comprehensive clinical program resulting in a large amount of data to be reviewed, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. COPD is a life-threatening lung disease and a major cause of serious long-term disability(1). We remain committed to bringing new therapies to patients who suffer from this condition.

Last month the FDA s Pulmonary-Allergy Drugs Advisory Committee (PADAC) endorsed the safety of both the 75 and 150 mcg doses and voted in favor of approving QAB149 75 mcg in the US, after Novartis presented data showing that QAB149 significantly improved lung function compared to placebo, with improvements seen five minutes after the first dose and lasting for 24 hours(2).

The efficacy of Arcapta Neohaler at 75 and 150 mcg was demonstrated in an extensive clinical trial program in a total of 1,282 COPD patients in five key Phase III trials lasting 12-26 weeks(2).

QAB149 is already approved at 150 and 300 mcg once-daily doses in more than 50 countries worldwide under the brand-name Onbrez® Breezhaler® for the maintenance bronchodilator treatment of airflow obstruction in COPD patients(3). 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).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as extension, to complete, extended, committed, or similar expressions, or by express

or implied discussions regarding potential marketing approvals for QAB149, or the timing of any such approvals, 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.

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.

References

(1) Sin DD, Stafinski T, NG YC, Bell NR, Jacobs P. The impact of chronic obstructive pulmonary disease on work loss in the United States. Am J Respir Crit Care Med. 2002; 165: 704-707.

(2) Novartis data on file. Indacaterol (QAB149) in Chronic Obstructive Pulmonary Disease Briefing Document. February 1, 2011.

(3) European Medicines Agency (EMA): Onbrez® Breezhaler® (indacaterol). Summary of product characteristics. 4 January 2011.

(4) Donohue JF, et al. Once-daily bronchodilators for chronic obstructive pulmonary disease: Indacaterol versus tiotropium. Am J Respir Crit Care Med 2010; 182:155-162.

(5) Kornmann O, et al. Once-daily indacaterol vs twice-daily salmeterol for COPD: a placebo-controlled comparison. Eur Respir J 2011; 37:273-79.

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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: March 23, 2011

By: /s/ MALCOLM B. CHEETHAM

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