NOVARTIS AG
Form 6-K
October 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 October 19, 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

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: 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

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Novartis receives Complete Response letter from FDA for QAB149, an investigational bronchodilator for COPD

- *US Food and Drug Administration (FDA) has requested additional information on dosing proposed for QAB149*

- *Novartis will continue to work with the FDA to gain US approval for QAB149*

Basel, October 19, 2009 Novartis has received a Complete Response letter from the US Food and Drug Administration (FDA) as part of the US regulatory review for QAB149 (indacaterol), an investigational once-daily bronchodilator for the treatment of adult patients with chronic obstructive pulmonary disease (COPD).

The FDA has requested additional information on the dosing proposed for QAB149. Novartis will work with the FDA to review already submitted data for QAB149 as well as recently available data to determine what, if any, further clinical trials would be required.

We will continue to work closely with the FDA to gain US regulatory approval for QAB149, which we believe could offer an important new treatment option for patients with COPD, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Our confidence in the benefit/risk profile of QAB149 is based on results of Phase III trials which showed QAB149 significantly improved lung function(1) in patients with this severe disease and provided clinically relevant improvement in symptoms such as breathlessness(2) compared to other bronchodilators.

QAB149 was submitted for US regulatory approval in December 2008 as a new once-daily bronchodilator for maintenance treatment of airflow obstruction in patients with COPD. The original submission was based on a Phase III clinical trial program with three pivotal studies and enrolled 4,400 patients with moderate-to-severe COPD.

In Europe, the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion in September 2009 supporting regulatory approval of QAB149 as a once-daily therapy with two doses (150 micrograms and 300 micrograms). The European Commission generally follows the recommendations of the CHMP, which is the scientific committee of the European Medicines Agency.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, would, believe, could, confiden generally follows the recommendations of, or similar expressions, or by express or implied discussions regarding potential marketing approvals for QAB149 (indacaterol) 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 will be approved for sale in any market. 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 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.

References

(1) Fogarty C, Hébert J, Iqbal A et al. QAB149 once-daily provides effective 24-h bronchodilation in COPD patients: a 26-week evaluation vs placebo and tiotropium. Poster presented at the European Respiratory Society (ERS) 2009 Annual Congress in Vienna, Austria, 12-16 September 2009.

(2) Mahler DA, Palange P, Iqbal A et al. QAB149 once-daily improves dyspnoea in COPD patients: a 26-week placebo-controlled study with open-label tiotropium comparison. Poster presented at the European Respiratory Society (ERS) 2009 Annual Congress in Vienna, Austria, 12-16 September 2009.

# # #

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

Rebecca Fisher-Pollard
Novartis Pharma Communications
+41 61 324 91 66
+41 79 426 46 84
rebecca.fisher-pollard@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone: +41 61 324 7944
Ruth Metzler-Arnold +41 61 324 9980
Pierre-Michel Bringer +41 61 324 1065
John Gilardi +41 61 324 3018
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188
e-mail: investor.relations@novartis.com

North America:
Richard Jarvis +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: 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: October 19, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting