NOVARTIS AG
Form 6-K
September 29, 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 25, 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):

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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 -

Novartis bronchodilator QAB149 recommended for approval in European Union to treat patients with chronic obstructive pulmonary disease

- *QAB149 is set to become the first COPD therapy in the EU that combines 24-hour bronchodilation(1),(2) from a once-daily dose with onset of action within five minutes(3)*

- *A Phase III study vs. tiotropium showed significant lung function benefit(1), improvements in COPD symptoms(4) and significantly more days free of relief medication use(5)*

- *COPD affects 210 million people globally(6), up to 82 million in Europe(7),(8), and is projected to become the third leading cause of death worldwide(9)*

Basel, September 25, 2009 Novartis has received a positive opinion recommending European Union (EU) approval of QAB149 (indacaterol) for maintenance bronchodilator treatment in adult patients with chronic obstructive pulmonary disease (COPD). When approved, QAB149 and its device, Concept-1, will be known as Onbrez® Breezhaler®(1).

QAB149 has the potential to be recognized as an important once-daily COPD treatment with a rapid onset of action, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. QAB149 provides COPD patients with greater lung function improvements and reductions in breathlessness compared to other bronchodilators. On approval, our plans are for QAB149 to form the foundation of a new portfolio of potential products designed to improve patients respiratory health.

The positive opinion for two dose strengths of QAB149, 150 mcg and 300 mcg, has been issued by the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMEA). The European Commission generally follows the recommendations of the CHMP and delivers its final decision within three months.

QAB149 is currently undergoing regulatory review in the United States, where the regulatory submission was filed in late 2008.

Results from pivotal Phase III trials, presented recently at the European Respiratory Society (ERS) 2009 Annual Congress in Vienna, showed QAB149 significantly improved lung function(1) and provided clinically relevant improvement in symptoms of breathlessness(4) compared to tiotropium, a current treatment option. Further data showed QAB149 provided a greater than 20 percent increase in days during which no relief medication was required(5), compared to tiotropium. Relief medication is used to treat acute episodes of severe breathlessness.

(1) Onbrez® Breezhaler® are the names for indacaterol and its delivery device, Concept1, which are pending approval in the EU.

COPD is a progressive, life-threatening respiratory disease(10) that affects 210 million people worldwide(6), and up to 82 million in Europe(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(10). 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 incurable, COPD is manageable, and improving airflow with the use of long-acting bronchodilators is central to symptomatic relief(11).

Data on all evaluated doses of QAB149 show a good overall safety and tolerability profile(12),(13). 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 when treatment was continued.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommended for approval, set to become, projected, recommending approval, will, potential, plans, designed to, projected, or similar expressions, or by express or i 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 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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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 25, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting