NOVARTIS AG
Form 6-K
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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 December 3, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

Novartis International AG

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- Investor Relations Release -

Novartis receives approval in the European Union for Onbrez® Breezhaler®, a new once-daily bronchodilator for patients with COPD

- *Onbrez® Breezhaler® demonstrated superiority to tiotropium1, formoterol2, salmeterol3; first new inhaled compound for treatment of COPD in seven years for EU patients*

- *Onbrez Breezhaler is only treatment for COPD to combine 24-hour bronchodilation1,2,3 from a once-daily dose with rapid onset of action within five minutes4,5*

- *COPD affects 210 million people globally6, up to 82 million in Europe7,8, and is projected to become the third leading cause of death worldwide9*

Basel, December 3, 2009 Novartis announced today that the European Commission (EC) has approved Onbrez Breezhaler (QAB149 or indacaterol) in both 150 mcg and 300 mcg doses as a new once-daily maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).

Onbrez Breezhaler has demonstrated greater improvements in lung function, breathlessness and quality of life compared to current therapies, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. The EC approval of Onbrez Breezhaler means this new and effective therapy will soon be available to people in the EU with COPD and, through better symptom control, will help them to live more active and productive lives despite their condition.

Onbrez Breezhaler, containing the active ingredient indacaterol maleate, is the first new inhaled compound for the treatment of COPD to be made available for EU patients in seven years. Additionally, it is the first and only treatment to demonstrate in clinical studies both 24-hour bronchodilation1,2,3 and a rapid onset of action within five minutes of inhalation4,5.

COPD is a progressive, life-threatening respiratory disease[10] that affects 210 million people worldwide[6], up to 82 million in Europe[7,8], the majority of whom are under the age of 65[11]. COPD impairs lung function resulting in chronic breathlessness. This leads to a profound, negative impact on patients ability to work and support families. COPD currently ranks tenth in overall disease burden, ahead of asthma and diabetes[12].

The EC based its approval of Onbrez Breezhaler on data from over 6,000 patients. This data included pivotal Phase III results showing Onbrez Breezhaler significantly improved lung function[1] and provided clinically relevant improvement in symptoms of breathlessness compared to tiotropium[13]. Recent data presented at the American College of Chest Physicians (ACCP) Chest Conference showed once-daily Onbrez Breezhaler also achieved significant improvements in lung function compared to twice-daily salmeterol, another current treatment option[3]. In addition, Onbrez Breezhaler provided better health status* and improved breathlessness compared with salmeterol[3].

Onbrez Breezhaler has shown good overall safety and tolerability, which is comparable to other current treatments[3,14,15]. The most common adverse drug reactions were nasopharyngitis, cough, upper respiratory tract infection, and headache[16]. These were in the vast majority mild or moderate and became less frequent as treatment was continued[16].

QAB149 was filed with the United States Food and Drug Administration (FDA) in late 2008. In October 2009, Novartis received a Complete Response letter from the US. The FDA requested additional information on the dosing proposed, which Novartis is working to address.

Improving the management of COPD is a priority focus for Novartis and Onbrez Breezhaler is the lead compound in an expected once-daily portfolio for the treatment of this growing public health issue. Novartis has three additional investigational treatments in its late-stage COPD portfolio, NVA237, QVA149 and QMF149. Novartis is also exploring new pathways in the treatment of COPD as part of an innovative, early-stage pipeline with disease modifying potential.

About COPD

COPD is commonly caused by cigarette smoke and other harmful fumes, and is characterized by a persistent obstruction of airflow in the lungs, resulting in breathlessness[10]. COPD is currently projected to become the third leading cause of death worldwide by 2020[9]. Bronchodilators are a group of drugs that widen the airways in the lungs and are considered the cornerstone of COPD treatment, relieving symptoms and preventing exacerbations. While incurable, COPD is manageable, and improving airflow with the use of long-acting bronchodilators is central to symptomatic relief[17].

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*For this study, health status was assessed using St. George s Respiratory Questionnaire, a standardized self-completed questionnaire for measuring impaired health and perceived well-being.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as projected, will, expected, exploring, potential, or similar expressions, or by express or implied discussions regarding potential marketing, additional marketing approvals for Onbrez Breezhaler 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 Onbrez Breezhaler will be approved in any additional markets, or that 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: December 3, 2009

By: /s/ MALCOLM B. CHEETHAM

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