NOVARTIS AG
Form 6-K
February 11, 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 February 10, 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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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 studies show Onbrez® Breezhaler® plus tiotropium provided greater increase in lung function than tiotropium alone

- *Two Phase III studies demonstrated efficacy benefits of combining once-daily Onbrez Breezhaler 150 mcg with tiotropium in patients with COPD(1),(2)*

- *INTRUST 1 and 2 studies add to comprehensive data supporting Onbrez Breezhaler as effective treatment for COPD with good safety profile*

- *Results to be presented at ATS congress in May, 2011*

Basel, February 10, 2011 Novartis has announced that two Phase III studies show that patients with chronic obstructive pulmonary disease (COPD) who were treated with once-daily Onbrez® Breezhaler® (indacaterol) plus tiotropium experienced significantly greater improvements in lung function than those treated with tiotropium alone(1),(2).

The INTRUST 1 and 2 studies met their primary endpoints by demonstrating significant improvements in lung function, measured by forced expiratory volume of breath in one second (FEV_1), for Onbrez Breezhaler plus tiotropium compared to tiotropium alone after 12 weeks (both $p<0.001$)(1),(2).

Previous studies have confirmed the efficacy of Onbrez Breezhaler as monotherapy, and these data show the potential for additional lung function benefits when two of the leading classes of treatment for COPD are combined, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. These data support the treatment approach of combining bronchodilators of different classes as recommended in the internationally recognized GOLD guidelines for managing COPD(3).

Onbrez Breezhaler is the only marketed once-daily long-acting beta-2 agonist (LABA), while tiotropium (Spiriva® HandiHaler®*) is a long-acting anti-muscarinic (LAMA), both indicated for the treatment of COPD. The two classes of medicines have different modes of action but both therapies are inhaled to provide bronchodilation, i.e. increased airflow into the patient s lungs.

INTRUST 1 and 2 were matching 12-week, randomized, double-blind studies involving a total of 2,276 patients with moderate-to-severe COPD (as defined by the GOLD 2007 criteria). One group of patients received Onbrez Breezhaler 150 mcg once-daily, while the other group received placebo. All patients concurrently received open-label tiotropium 18 mcg once-daily. The incidence of adverse events was similar for the two arms of the studies(1),(2).

Efficacy and safety data will be presented at the American Thoracic Society congress in Denver, Colorado in May 2011.

Onbrez Breezhaler was first approved in November 2009 in the European Union, where it is indicated for the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD(4). It is now approved in more than 50 countries and has been launched in 13 European countries, with additional launches planned in 2011. The application for US approval (under the trade name Arcapta® Neohaler®) is expected to be reviewed by an FDA Advisory Committee in March 2011.

COPD is a progressive, life-threatening disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. COPD affects 210 million people worldwide(5) and is projected to be the third leading cause of death by 2020(3). Although often considered a disease of the elderly, research has shown that a majority of COPD patients are under the age of 65(6) when they are likely to be at the peak of their earning power and family responsibilities.

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* Spiriva® and HandiHaler® are registered trademarks of Boehringer Ingelheim Pharma GmbH & Co. KG.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, planned, expected, projected, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Onbrez Breezhaler, regarding potential approvals to sell Onbrez Breezhaler in additional markets, regarding the timing for such approvals, or regarding potential future revenues from Onbrez Breezhaler. 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 with Onbrez Breezhaler 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 submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Onbrez Breezhaler will be approved for sale in any additional markets. Neither can there be any guarantee regarding the timing of any such potential approvals. Nor can there be any guarantee that Onbrez Breezhaler will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Onbrez Breezhaler 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) http://www.novctrd.com/ctrdWebApp/clinicaltrialrepository/displayFile.do?trialResult=3901

(2) http://www.novctrd.com/ctrdWebApp/clinicaltrialrepository/displayFile.do?trialResult=3903

(3) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2009. Available at: http://www.goldcopd.com/Guidelineitem.asp?l1=2&l2=1&intId=2003. Last accessed 9 February 2011.

(4) Onbrez Breezhaler (indacaterol) Summary of Product Characteristics. June 16, 2010.

(5) WHO. Factsheet No 315: Chronic obstructive pulmonary disease (COPD), Available at: www.who.int/mediacentre/factsheets/fs315/en/index.html. Last accessed 9 February 2010.

(6) Data on file. Novartis Pharma AG.

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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: February 10, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting